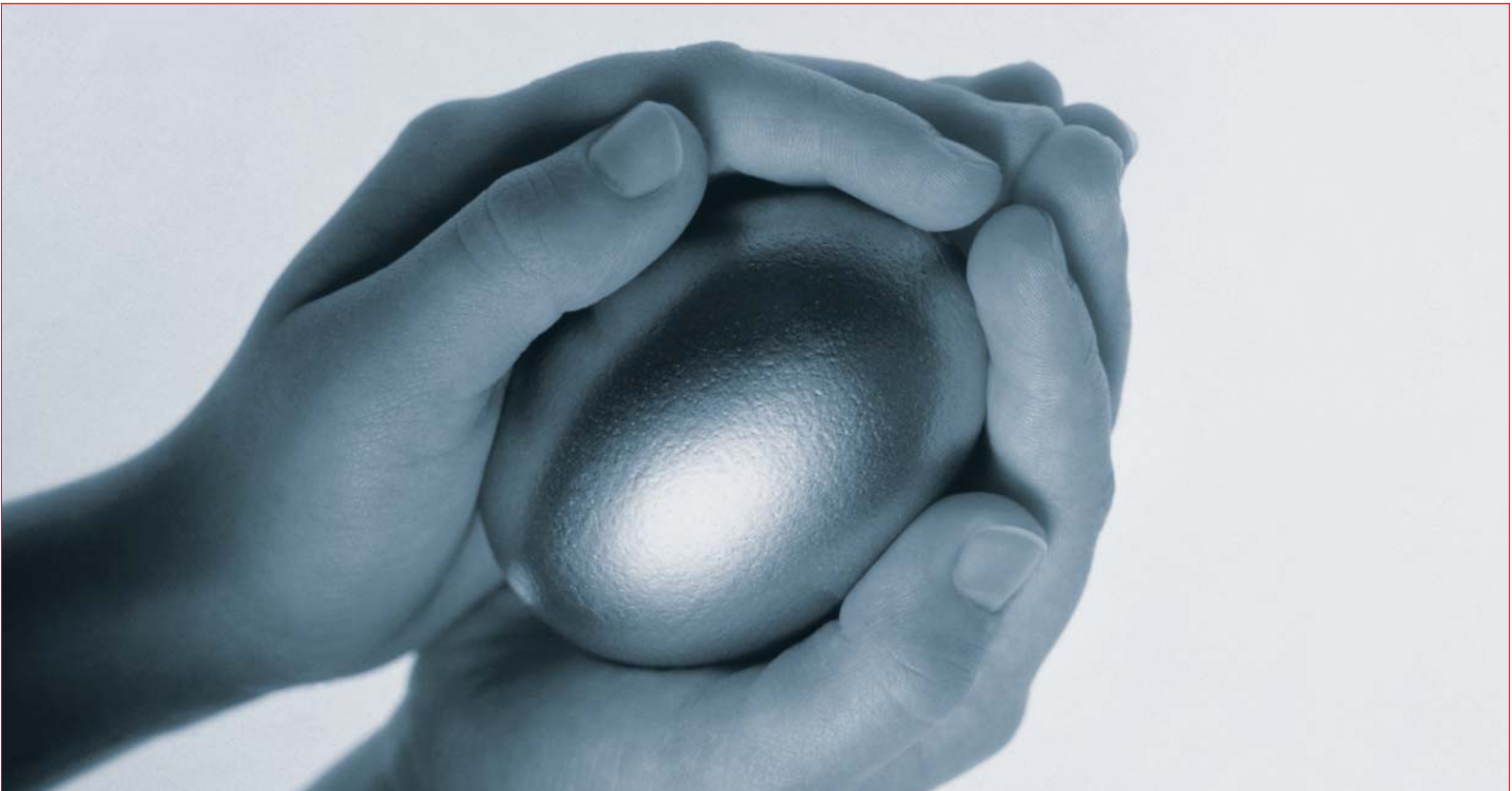




ECLECTICA

Eclectica™

User Manual



ADALTIS



U S E R M A N U A L

Release
OpenLAB
5.2.0

Rev.A



ADALTIS

ECLECTICA[™] User Manual
Software Release OpenLAB 5.2.0

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SECTION 0

INTRODUCTION

Preface

The ECLECTICA™ system is the latest innovation in the field of laboratory instrumentation offered by Adaltis Srl.

In order to assure proper operation of the instrument, the user must observe simple standards and procedures, schedule maintenance and respect the basic principles of its intended use.

In order to guarantee these conditions, Adaltis Srl provides the present Manual as the main reference for all functional and technical aspects.

Adaltis Srl's Client Service Department is at the user's disposal for any support requirements.

Intended use

The ECLECTICA™ system runs doses for determining Immunochemistry and Clinical Chemistry. The ECLECTICA™ system is intended for use in in-vitro diagnostics.

Warning

The ECLECTICA™ system software and documentation are copyright protected. All rights reserved.

The software and documentation have been developed exclusively for use with Adaltis Srl instrumentation intended for in vitro diagnostics applications.

Any copying or reproduction, in any form, or all or part of these materials for any other use than archiving with the express authorization of Adaltis Srl is forbidden.

Illustrations

The sample printouts/screenshots and the graphics contained in this Manual are intended purely as illustrations/information and as graphics. Adaltis Srl provides no guarantee regarding the accuracy or reliability of the information given in the said printouts, screenshots and graphics.

Certificate of conformity

The ECLECTICA™ system is conforming with the requirements of Directive IVDD 98/79/EC regarding in vitro diagnostics equipment and the applicable harmonized standards included therein.

List of Trademarks and Patents

ECLECTICA™ is a trademark of Adaltis Srl.

The ECLECTICA™ system is covered by the following patent:

- Solid phase container Grant Nr.57366.

Information about the manual

This Manual contains the full information required to maintain the functionality of the ECLECTICA™ instrument and to ensure correct use of its software.

The Manual is provided together with the instrument and forms an integral part of the system. It must be used as a reference inasmuch as it provides the general description of the system and detailed operational, maintenance and troubleshooting procedures. Before using the instrument, read the manual and familiarize yourself thoroughly with it.

The details and user instructions for the individual assays are given in the user instructions provided in the "ECLECTICA™ Kit Assay Manual" (code: ECLP4050000018).

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Purpose of the Document

This document is the User Manual for the ECLECTICA™ system.

It is addressed to technical laboratory personnel who have experience and practice in using automatic laboratory instrumentation.

Please read this Manual throughout.

Please keep this manual close to the ECLECTICA™ instrument during daily laboratory activity.

Symbolism

Wherever specific attention is required in reading this Manual, the following symbols are used.

The symbol "NOTE", in boldface, is used to highlight information.

The symbol "  WARNING" in boldface is used to highlight risks and hazards.

NOTE: The manufacturer, Adaltis Srl, declares that the information contained in this manual only permits the instrument to which it refers to be used correctly if the user has taken a specific training course as indicated by the manufacturer.

How to use the Manual

This Manual contains full instructions for using and maintaining the ECLECTICA™ system.

Adaltis Srl has created the Manual as a support during training and an essential reference during everyday use of the ECLECTICA™ system.

A brief summary of the contents of the 11 Sections of which the Manual is composed is given below.

Section 1: Safety

The user must read this Section, which describes the general safety precautions to be observed when using the instrument and its consumable/disposable materials.

Section 2: Labelling

This Section describes the safety symbols applied to the instrument itself.

Section 3: Installation

The user must read this Section, which describes the instrument's installation procedure.

Section 4: Operating principles

Read this Section to gain a better understanding of the system: what it measures, how it makes the measurements and how they are transformed into useable data and reports.

Section 5: Functions

This Section defines every component of the system and explains its purpose and operation.

Section 6: Operating precautions

The user must read this Section, which describes the precautions to be observed when preparing/running assays and the associated risks.

Section 7: Operation

This Section should be referred to in order to learn the operation of the instrument and how to run assays. It must be studied during training and referred to frequently thereafter.

Section 8: Maintenance

This Section specifies all the maintenance operations required for correct operation of the instrument.

Section 9: Troubleshooting

The user will refer to this Section in order to determine what action to take in response to the error messages displayed on the instrument's screen.

Section 10: Technical specifications

This Section contains the technical specifications, including dimensions, technical characteristics and electrical and environmental requirements.

Section 11: Supplementary information

This Section contains information regarding warranty restrictions, lists of spare parts/accessories/consumables, and ordering information.

SECTION 1

SAFETY INSTRUCTIONS

The manufacturer, Adaltis Srl, reminds you that failure to observe the prescriptions provided in this Section may damage the instrument and the environment, injure the user, and produce incorrect results.

This Section describes the following subjects:

- Operational precautions
- Types of risks and consequent instructions
- Procedure for stopping the system

Detailed information on these subjects is given in the individual Sections into which the Manual is divided.

The user must strictly observe all information contained in this manual.

The user must not make any type of modification to the instrument or tamper with the software without the prior authorisation of the manufacturer, Adaltis Srl.

Adaltis Srl is not liable for damages consequent on improper use of the instrument and reserves the right to take legal action to protect its interests.



WARNING: The user must strictly observe all information contained in this manual. Failure to observe the precautions and restrictions on use given in Section 6 “Restrictions” may result in damage to the instrument and environment, injury to the user and generate incorrect results.

Operational precautions

The ECLETICA™ system (instrument and consumables) is intended exclusively for in vitro diagnostic use.

The ECLETICA™ system (instrument and consumable materials) is designed for professional applications. It must therefore be used only by expert laboratory personnel.

Carefully read the general warnings given below in order to ensure proper use of the system.

- Make sure that all installation operations are carried out by technical personnel authorised by the manufacturer, Adaltis Srl
- Perform the maintenance operations described in Section 8, “**Maintenance**”. Maintenance and/or repair procedures that are not specified in the documentation provided by the manufacturer, Adaltis Srl, must not be performed.
- Follow all of the precautions normally adopted in the laboratory (Good Laboratory Practice).
- Use only the consumables recommended by the manufacturer.
- Take all appropriate care in preparing and utilising samples and consumables.

NOTE: Carefully read the information on this subject given in the specific user’s instructions for every assay contained in the “Application Protocols Manual” (p/n: ECLP4050000018)

The following paragraphs describe the precautions and restrictions on use regarding:

- transport and storage;
- operation;
- use of consumables/disposable materials;
- preparation of samples;
- maintenance.

Transport and Storage

The instrument must be transported only in its original packaging, supplied by the Manufacturer Adaltis Srl, and consisting of a wooden crate.

Refer to Section 3, “**Installation**”, and Section 10, “**Technical Specifications**”, for information about proper storage of the instrument.

Installation

Qualified technical personnel authorized by Adaltis Srl must carry out the installation, checking and instrument calibration.

The qualified technical personnel must make sure that the instrument's positioning complies with the environmental and electromagnetic specifications that the instrument's specifications require. The instrument may only be moved to a significant extent (from one surface to another) by qualified personnel.

The instrument must sit on a flat and perfectly horizontal surface, located:

- away from currents of air;
- away from direct sunlight and sources of heat

Leave sufficient free space around the instrument to allow its internal electrical equipment to cool efficiently, ensure accurate process area temperature control and leave free access for maintenance.

Refer to Section 3, “**Installation**”, and Section 10, “**Technical Specifications**”, for more information.

Before installing the instrument, the Adaltis technician must ensure that the location of the instrument is compliant with the electrical and environmental safety specifications given in the Section 10: **Technical Specifications**.

Operation

For correct use of the ECLECTICA™ instrument, make sure to:

- Connect the instrument to a standards compliant power source.

NOTE: the instrument is designed so as to not be affected by rapid transitory power supply variations.

- Do not install applications other than those necessary for normal operation of the ECLECTICA™ instrument on the dedicated PC unless with the express approval of the Adaltis Srl Technical Department.



WARNING: Other programs residing in memory, such as Power Managers, Screen Savers and Antivirus applications, may affect the operation of the system and must therefore not be installed.

- Pay specific attention to the instructions provided by the manufacturer for the correct operations used to turn the instrument on and off (see Section 7 "**Operation**").
- Do not disconnect the instrument from its power supply while it is operating.
- Check the position of the vials of reagent and the sample tubes inside the instrument.



WARNING: Incorrect positioning could generate errors in calculating the dispensing volumes.

- Do not allow foam to form either when homogenizing the solutions or when loading the reagents and sample tubes into the instrument.



WARNING: Bubbles and foam can affect the operation of the level sensor and cause incorrect volume dispensing or dispensing failure, thus resulting in errors.

- Prevent liquids from leaking inside the instrument's work area.
- Do not replace or reposition reagents and samples after their barcodes have been read (active recognition).
- Make sure that all caps on the reagents have been removed so as to prevent collisions with the sampling needles.
- Check that a sufficient number of reaction cells have been loaded onto the instrument.
- Respond to the system's messages concerning the level of liquid wastes (liquid waste tank) and solid waste (Reaction Segments) during use.

Using Consumables (Reagents)

For correct use of ECLECTICA™ consumables:

- Do not use other consumables than those specified by Adaltis Srl;
- Use all the consumables (Reagents) within their period of validity (see label);



WARNING: Use of a reagent after its expiry date may give incorrect results.

- Use the consumables in their original packages, do not pour the reagents into previously used containers, do not mix reagents from different lots
- Observe the instructions for preparing, using and storing the consumables given in the assay User Instructions in the “Application Protocols Manual” (p/n: ECLP4050000018)
- Observe the restrictions of use given in the instructions for every assay contained in the “Application Protocols Manual” (p/n: ECLP4050000018)
- Contact the Adaltis Hotline Service if you receive packages of consumable materials not shipped in compliance with the given specifications.

Use of disposable materials (accessories)

The disposable materials supplied by the Manufacturer Adaltis Srl are the **Reaction Segments** (reaction cells). These are disposable plastic containers in which all assay phases except photometric reading are run. Each package contains 100 segments of 24 Cells each (2400 reaction Cells).

NOTE: Do not reuse or substitute disposable materials. All disposable materials are to be sheltered from dust and sources of heat.

Preparing the Samples

Consult the User Instructions for every assay contained in the "Application Protocols Manual" (p/n: ECLP4050000018) in order to determine the correct type of sample for each assay and the respective handling and storing methods.



WARNING: Failure to observe the sample selection and treatment instructions can yield incorrect results.

The **sample volume** necessary for executing the assay may vary based on the analyte to be determined. Consult the specific User Instructions for every assay contained in the "Application Protocols Manual" (p/n: ECLP4050000018) and Section 7 of this manual, "**Operation**", for information about the sample volume.

Samples

Taking and processing samples

The following recommendations for handling and storing blood samples were provided by the National Committee for Clinical Laboratory Standards (NCCLS – Doc. H18-A):

- Take the blood samples following the normal precautions for collecting biological fluids;
- In the case of serum samples, allow the samples to adequately and fully coagulate before centrifuging them.

NOTE: In order to avoid incorrect results due to the presence of fibrin, make sure the coagulation process is complete before the samples are centrifuged. Some samples, particularly those of patients undergoing therapy with anticoagulants, may require a longer time for coagulation.

- The test tubes must be kept closed and in a vertical position;
- Do not use samples that have been left at ambient temperature for more than 8 hours;
- Hermetically seal and refrigerate the samples (2°C...8°C) if the assay is not made within 8 hours;
- Freeze the samples at –20° or below if the assay is not performed within 48 hours;
- Thaw the samples only once and thoroughly mix after thawing
- Use of an ultracentrifuge is recommended for clarifying the lipaemic samples.

NOTE: Haemolysed samples may indicate unsuitable processing of the sample prior to its arrival at the laboratory; the results must be interpreted with circumspection for this reason.

Serum

Collect 5 ml of venous blood in a glass test tube without additives. Have it coagulate at ambient temperature (18°C...25°C). Centrifuge, separate the fraction consisting of the serum and store.

Plasma

Collect 5 ml of venous blood in a test tube made of glass or plastic containing Heparin as an anticoagulant. Centrifuge, separate the fraction consisting of the plasma and store.



WARNING: Before loading the sample into the ECLECTICA™ system, make sure that it is free of particles, suspensions, filaments, clots, fibrin, air bubbles and foam.

Volume

The volume of the sample is specified in the user Instructions for each individual assay. This volume does not include the dead volume (unusable volume in the sample container) or the additional volume required for executing replicates or other tests to be run on the same sample.

Maintenance

The user must perform the daily and weekly maintenance procedures pursuant to the instructions given in Section 8, "**Maintenance**", throughout the instrument's lifetime.

The manufacturer reminds you that periodic visual inspection of the instrument is the first and easiest way of ensuring the best performance of the instrument.

To ensure correct maintenance, carefully read the instructions given in Section 8 "**Maintenance**", and in particular:

- use only the recommended wash and disinfecting solutions with the proper concentration;
- periodically clean the instrument parts according to the methods described;
- Immediately remove any splashes or leaks of liquid from the work area.



WARNING: Before cleaning or decontaminating the equipment using methods other than the ones recommended by the manufacturer, contact Adaltis Srl to check that the proposed procedure does not risk damaging the instrument.

Operational precautions

The precautions and restrictions regarding the consumables (reagents) and samples to be used with the ECLECTICA™ instrument are described in this Section.



WARNING: All reagents provided with the ECLECTICA™ instrument are for professional use only. They must be used only by expert laboratory personnel in conformity with GLP rules. Do not combine reagents from different lots.

Operational precautions

- Do not pipette with your mouth.
- Do not smoke, eat or apply cosmetics in those areas where the kit's reagents are handled.
- Avoid inoculation, contamination of mucous membranes or the formation of aerosol.
- Laboratory gloves must be worn when handling the patients' samples or liquid or solid wastes.

Types of risks

The following paragraphs describe the various types of risk associated with the use of the ECLECTICA™ instrument and the relative safety instructions.

- Biological risk
- Chemical risk
- Electrical risk
- Mechanical risk
- Risk of lesion

The instrument is equipped with labels to identify the positions and types of the various hazards.

For further details, refer to Section 2: "**Labelling**".

Biological risk

Analysis of the immunological assays increases the risk of exposure to potentially infected substances. For the sake of safety it is necessary to meticulously observe the rules for handling samples and reagents of human origin.

Adaltis Srl reminds you that:

- using the instrument does not rule out exposure to the risk of contamination, so the instrument must always be considered potentially infected;
- all parts of the instrument that may come into contact with blood, serum and other biological fluids, reagents and Controls must be handled as potentially infected materials;
- all waste materials must be handled as though they are potentially infected.

The manufacturer, Adaltis Srl, also assumes that all precautions and warnings normally used in an analysis laboratory (Good Laboratory Practice) are followed.

In order to avoid risks, every user must observe the biological safety rules in the following conditions:

- during handling of samples, Reagents, Calibrators, Controls and Diluents;
- during maintenance and when handling and disposing of waste;
- in case of spills and splashes (prevention and cleaning);
- during disposal and disinfection.

The user and other personnel working in the proximity of the instrument for any reason must remember that:

- the Specific Reagents, Controls, Calibrators and Diluents may contain substances of human origin;
- all substances of human origin are potentially infected; none of the known analytical methods can absolutely guarantee that products of human origin do not transmit infections;
- some ECLECTICA™ system reagents contain materials of animal origin. Although these are certified as coming from healthy animals, handle them with the same precautions taken when handling potentially infected samples.

The user and other personnel working in the proximity of the instrument must:

- always wear laboratory clothing, disposable gloves and protective goggles when handling the samples to be analysed;
- not eat, drink or smoke in the laboratory.

Furthermore, take specific care when using, maintaining and disposing of the following components of the instrument (for a detailed description of the instrument's components, see Section 5: “**Functions**”):

- Reaction Cell wash system;
- Sampling Needles;
- Waste Discharge Tank;
- Reaction Segments;
- Wash trap.

These parts may be contaminated because they come into contact with biological fluids and reagents.

Refer to Section 8, “**Maintenance**”, for the correct disinfecting procedure.

Every tool/fixture used during the technical operations must be disinfected with the correct disinfecting procedures before being put away and stored.

Disposal

The instrument and its components must be disposed of in observance of national regulations, referring to the local environmental authorities. Before disposal, the instrument and its components must be decontaminated as explained in Section 8, “**Maintenance**”.

All waste materials, whether liquid or solid, must be disposed of in compliance with local laws and regulations.

Chemical risk

Some reagents are classified as dangerous preparations according to the established legislation.

Every user must follow the rules of protection from chemical risk in the following conditions:

- during handling of samples, Reagents, Calibrators, Controls and Diluents;
- during maintenance and when handling and disposing of waste;
- in case of spills and splashes (prevention and cleaning);
- during disposal and disinfection.

Refer to the instructions given on the labels of the bottles, in the specific User Instructions for every assay contained in the “Application Protocols Manual” (p/n: ECLP405000018) and on the Safety Data Sheets.

Disposal

All waste materials, whether liquid or solid, must be disposed of in compliance with local laws and regulations.

Electrical risk

The manufacturer, Adaltis Srl, declares that all internal parts of the instrument are designed and made so as to prevent all possible risks for the user, in accordance with established legislation.

The instrument does not constitute an electrocution hazard if installed without modification, and if connected to an electrical power supply having the specified characteristics. The instrument must be grounded.

See Section 3, “**Installation**”, and Section 10, “**Technical Specifications**”, for details regarding the electrical power supply.

Component replacements or repairs must be carried out by technical staff authorized to do so by the manufacturer, Adaltis Srl.



WARNING Do not remove the instrument's guards and enclosures.

Mechanical risk

The User must learn and remember the basic rules to follow when working with mechanical equipment:

- be thoroughly familiar with the system and scrupulously follow the user and maintenance instructions
- Make sure that all covers and guards are operational.

Component replacements or repairs must be carried out by technical staff authorized to do so by the manufacturer, Adaltis Srl.

Risk of lesion

The laser light generated by the reagent/sample barcode reader may damage the eyes. Do not stare into the source of light.

An accidental glance into the beam of light is not harmful.

Emergency stop procedure

In case of emergency:

- Use the switches located on the back of the instrument.
- Set both switches to OFF, indicated by the symbol “O” on the switch plate.
- Remove the power cord from the socket-outlet.

NOTE: when the instrument is next switched on, all data regarding the current assays will be lost.

SECTION2

LABELLING

The ECLECTICA™ instrument bears a number of labels which:

- Identify the instrument
- Bear its CE Mark
- Bear safety warnings (symbols and phrases) to which the User must pay attention

Instrument Identification Label

This label identifies the manufacturer, the instrument type, the serial number, power supply and the fuse specifications.

It is to be found on the rear of the instrument.



Disposal of Electrical and Electronic Waste Label

The adhesive label bearing this symbol is located on the rear of the analyzer, close to the instrument identification.

It informs the User regarding Directive 2002/96/CE and Decree Law 25 July 2005, No. 151, regarding disposal of electrical and electronic waste.

This Directive requires that electrical and electronic products be disposed of in an adequate manner, so as to avoid any negative impact on the environment. This makes it compulsory to use a differential waste collection system, as well as special electrical and electronic equipment waste (EEEW) treatment and disposal methods.



CE Mark Label

This label indicates compliance of the instrument to the essential safety requirements envisaged by the applicable European Directives.

It is to be found on the rear of the instrument.



Safety Warning Labels

The labels given below are placed on the instrument in order to ensure it is correctly and safely used. It is important that the user knows their meanings and positions. The labels also identify the position of the potential danger.

Label 1: Generic Hazard

This label is located on the instrument's cover (swing door and sliding window).

It informs the user of the potential risk associated with opening the cover, thus rendering the instrument's work area accessible.



Label 2: Electrical Hazard

This label is on the back of the instrument.

It informs the user of the electrical hazard. It tells the user to disconnect the power supply before opening the instrument.

**Label 3: Moving Parts Hazard**

This label is applied to the work surface next to the Samples carousel and the reaction Cell Washing System.

It informs the user of the risk associated with certain moving parts:

- Sampling Needles
- Samples Carousel.



Label 4: Bio-hazard

This label is applied to the working surface and to the hatch in which the waste tank is located.

It informs the user of the possible risk of biological contamination in the area in question (work area, waste tank housing).

**Label 5: Waste Tank Bio-Hazard**

This label is located on the waste tank door.

It informs the user of the possible risk of biological contamination related to the waste tank.

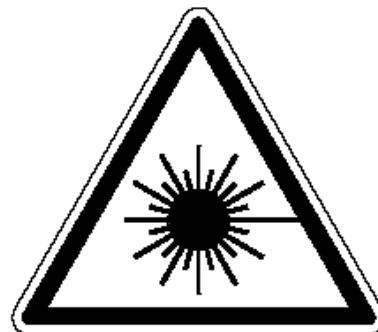


Label 6: Infection hazard

This label is located next to Label 3: Moving parts hazard.
It informs the user of the possible risk of biological contamination associated with contact with this part of the instrument.

**Label 7: Laser Light Hazard**

This label is on the bar code reader.
It informs the user about the hazard associated with the laser beam and the characteristics of the laser source.

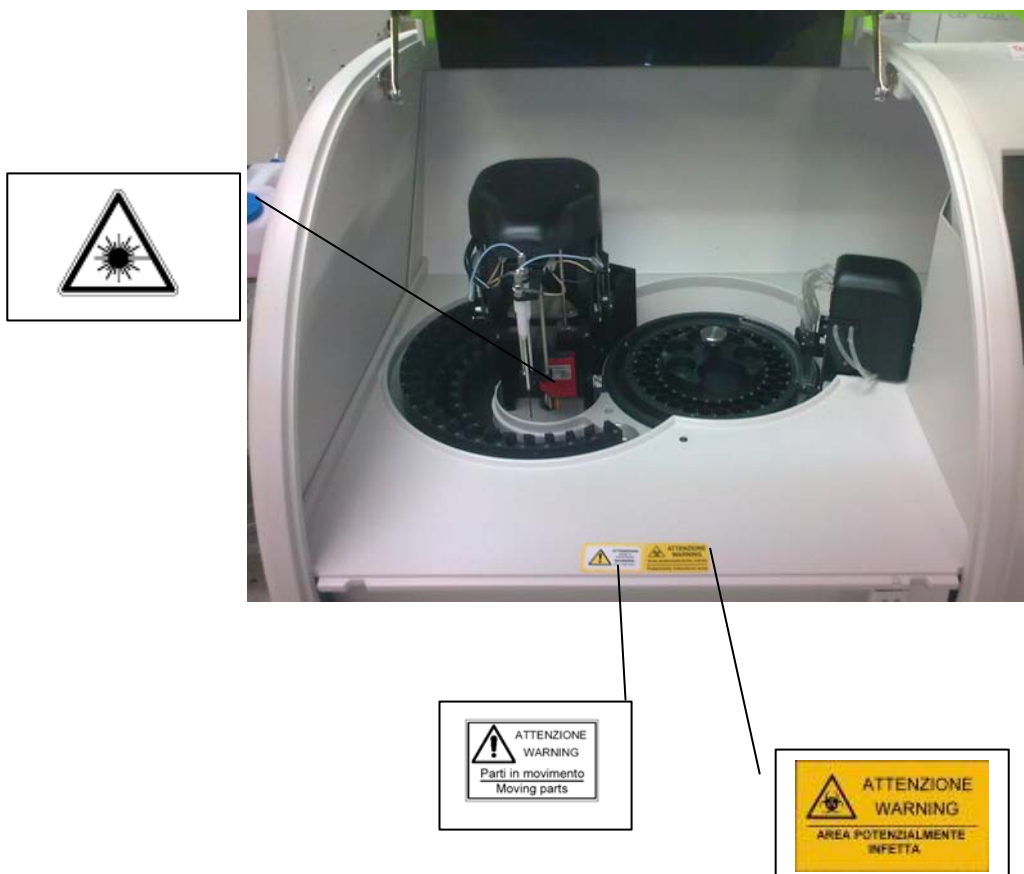


Avoid exposure laser light is emitted
from this aperture.
*Evitare l'esposizione, luce laser
emessa da questa apertura.*

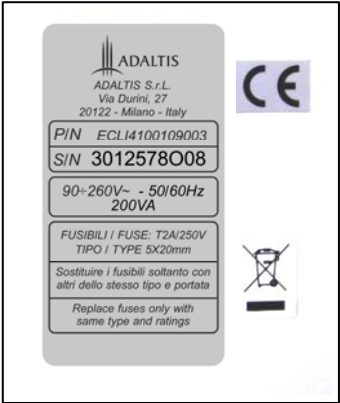
Layout of labels on the instrument

We show below the locations of the above labels on the instrument.

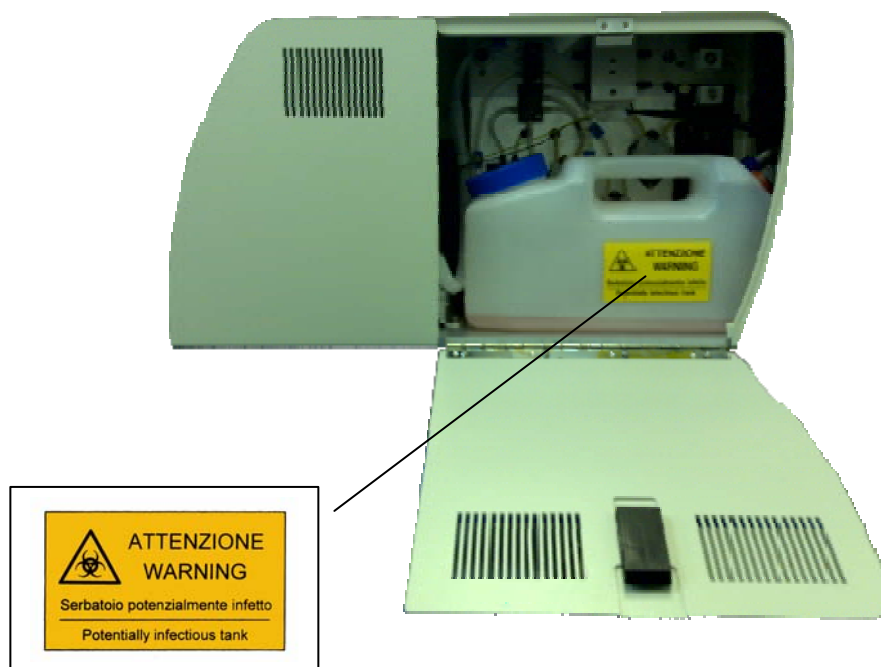
Front view



Rear view



Side view



SECTION 3

INSTALLATION

Preparation before Installation

Before removing the packaging, check that all mechanical and environmental requirements are observed.

Mechanical Constraints

The ECLECTICA™ instrument requires a table at least 1.5 metres long and at least 80 cm deep. The table must be stable so as to prevent undesirable oscillations or vibrations when using the instrument. Provide:

- At least 1 metre headroom above the work surface.
- Workspace of at least 50 cm around the instrument. In any case, the two cooling fans located on the lower part of the rear housing must have a free space around them of at least 10 cm relative to a wall of at least 30 cm dividing the instrument from other laboratory equipment (for details, see Fig. 3.1).

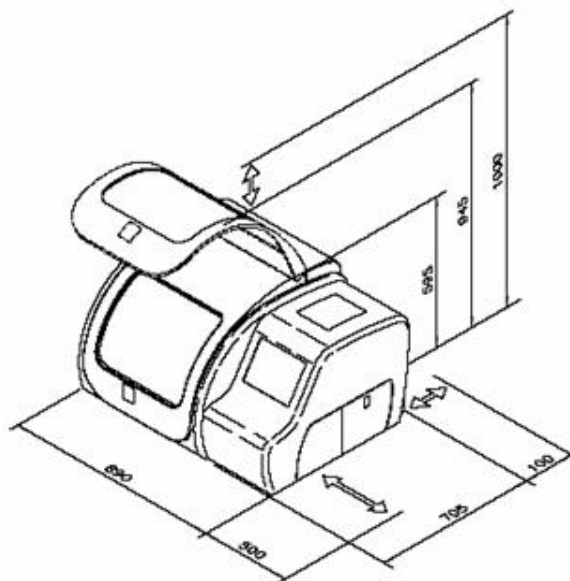


Fig. 3.1

Environmental Constraints

The room where the instrument is installed should be equipped with an air conditioning system so as to have a constant temperature (from 15° to 35°C) and a correct degree of humidity (from 20% to 80% of relative non-condensing humidity).

Avoid direct exposure to sunlight.

The instrument must be installed far away from heat sources.

Transport

The ECLECTICA™ instrument and its included materials are shipped in the original packing consisting of a wooden crate. This packing can be reused if the instrument has to be moved or sent back.

Checking for Damage Due to Transport

Check that the packing is not damaged upon receipt of the instrument. Any damages caused by transport must be immediately notified to the forwarding company that transported the goods, and be promptly recorded.

Once the forwarding company has delivered the goods, responsibility for its integrity lies with the receiver.

Check that the packaging is not damaged. A SHOCKWATCH® label is applied to the packaging; the bulb turns red if the package has been handled abnormally during transport. If this is the case, or if the packaging is damaged but the SHOCKWATCH® has not tripped or is missing, proceed as follows:

- Do not refuse the shipment
- Detail the problem in writing
- Do not remove the instrument from its packing and immediately request inspection to be done by the forwarding company within 15 days from receipt. If the shipment is international, inspection must be requested within 3 days from receipt
- Inform the Adaltis Hotline Service.

NOTE: The procedure described above may vary with local regulations and/or with specific agreements made with the forwarding company.

Storage Information

In order to store the instrument properly, it is advisable to keep it in a dry room and to comply with the environmental requirements given in Section 10 "***Environmental Requirements for Storage***".

The instrument must be stored only in its original packaging. Only specialised personnel may perform storage operations.

Refer to the User Instructions for every single analyte contained in the "Application Protocols Manual" (p/n: ECLP4050000018) with regards to the storage consumable materials.

Provided Materials

The following materials are supplied with the instrument, divided into:

- Consumables/Disposable Materials.
- Optional materials.
- Materials supplied with the instrument.

Consumable Materials

In order for the instrument to be properly used, only consumable materials manufactured and supplied exclusively by the manufacturer, Adaltis Srl, or by its dealers, intended specifically for use on the ECLECTICA™ instrument, may be used. In particular, the following products are considered consumable materials:

IMMUNOLOGY CONSUMABLES

Common Reagents

Reagents required to run all assays:

- A package containing one Substrate Solution, one Stop Solution, one Separation Agent and a Smart Card.
- A package of Systemic Wash Solution and Immunoassay Washing Buffer.

Specific Reagents

Reagents required to run a specific assay:

- Each package contains the Specific Reagents, Controls and the Smart Card on which are stored the specific data for the analyte to be assayed.

Calibration Set (calibrators):

Reagents required for running the Calibration Curve for a given assay:

- Each pack contains the set of calibrators (5-7) necessary to execute a calibration curve and a Smart Card containing the necessary data.

Diluents

Reagents required for diluting the sample (where required):

- Each package contains dilution solutions and a Smart Card.

CLINICAL CHEMISTRY**Common Reagents**

Reagents required to run all assays:

- A package of Systemic Wash Solution.

Please note that even if you are not running IA tests, the Immunoassay Wash Solution Bottles has to be replaced with a distilled water one.

Specific Reagents

Reagents required to run a specific Clinical Chemistry:

- Every package contains the Specific Reagents and a Smart Card with the data for the analyte in question.

Parametric Multicalibrators

- Each package contains the multicalibrator bottles and a Smart Card with the corresponding reference values. Refer to Section 7, “**Reagent/Control/Calibrator barcodes**”, for more information about the analytes contained in the multicalibrator.

Calibration Set (calibrators)

Reagents required for running the Calibration Curve for a given analyte:

- Each pack contains the set of calibrators necessary to execute a calibration curve and a Smart Card containing the necessary data.

Diluent

Reagent required for diluting the sample (always required for the reagent blank).

For correct use of ECLECTICA™ consumables:

- Do not use other consumables than those specified by Adaltis Srl. All consumables must be used within their specified expiry dates.
- Use the consumables in their original packages: do not pour the reagents into previously used containers. Do not mix reagents from different lots.
- Observe the instructions for preparation, use and storage of the consumables given in the dosage User Instructions in the "ECLECTICA™ Assay Manual" (code ECLP4050000018).
- Observe the restrictions of use for the individual assays given in the user instructions provided in the "ECLECTICA™ Assay Manual" (code: ECLP4050000018).



WARNING: failure to observe the above instructions may generate incorrect results.

- Contact the Adaltis Hotline Service if you receive packages of consumable materials not shipped in compliance with the given specifications.

Other consumables

In addition to the above materials, the following other consumables are required to use the instrument correctly.

Materials supplied by Adaltis Srl:

- Cleaning Kit: Solution for cleaning of hydraulic circuits and sampling needles, to be used for the wash cycle specified in the maintenance procedure (see Section 11: "Supplementary Information").
- Thermal paper for the internal printer.

Necessary materials supplied by Adaltis Srl upon request:

- 12 x 75 mm test tubes used for samples and multicalibrators.

Necessary materials not supplied by Adaltis Srl:

- 12/16 x 50/100mm test tubes for pre-diluting the samples and multicalibrators.
- Distilled water: for the wash cycle specified in the maintenance procedure.
- Sodium hypochlorite: solution used for the disinfection cycle specified in the maintenance procedure.

Disposable Materials

The disposable materials are the **Reaction Segments**, disposable plastic containers in which all assay phases except photometric reading are run.

Optional materials

The ECLECTICA™ instrument is equipped with an internal thermal matrix printer that provides a standard printout of the results.

It is possible to request an external printer provided with USB lead for customized printouts.

Materials supplied with the instrument

Each instrument is equipped with:

- 1 Waste tank
- 1 bottle for Systemic Wash Solution
- 1 brown bottle for washing the Substrate line
- 1 white bottle for washing the Stop Solution line
- 1 bottle for IA Washing Buffer

Also supplied with every instrument is a box containing:

- 1 Touch Screen Pen.
- 1 Mouse duplicator
- 1 package of Adaptor for sample tubes (65 pieces)
- 1 roll of thermal paper (for the internal thermal printer)
- 1 pack of Reaction Segments (24 segments)
- 1 220 Volt Electric Power Cord
- 1 115 Volt Electric Power Cord
- 1 "System recovery Disk" CD
- 1 ECLECTICA™ software installation CD.
- 1 CD containing the user manual in the available languages
- 1 Kit of Tubes
- 1 Kit of Fuses

Each instrument is supplied with:

- 1 User Manual (instrument User Instructions)
- 1 Instruction Manual for using ECLECTICA™ Kits (containing the User Instructions for every single analyte)

Installation

Correct installation assures good operation of the instrument.

The installation must be done by technicians authorized to do so by Adaltis Srl.

The installation procedure is described in the following paragraphs.

Detailed safety instructions are given in Section 1: “**Safety**” and Section 2: “**Labelling**”.



WARNING: If the instrument has to be moved to a new position or office after installation, contact the Adaltis Srl Hotline.

Unpacking

Use a crosshead screwdriver to undo the bolts securing the side panels, then lift off the packaging and remove the two side panels securing the instrument. Take out the box containing the materials supplied with the instrument.

At least two people are necessary to move the instrument from its wooden base to the work table.

Place the instrument on the work surface (where the instrument will have to operate).

Check that the serial number of the instrument corresponds to the one on the transportation document; if it does not, contact the Adaltis Srl Hotline.

NOTE: Store the original packing in case you want to store or move the instrument in the future.

Electrical Connections

The instrument comes with a three-wire, three-pole Bulgin F power cable for 230 V AC power supply.

The power cable must be connected to a wall plug with ground terminal. The power supply plug has two 3.15 A protection fuses.



WARNING: In accordance with the safety regulations listed at the beginning of this manual, the instrument must be connected to an earth point in order to reduce the risk of electric shock.

Hooking up the Waste Tank/Bottles

The instrument must be connected to the Waste Discharge Tank and the bottles containing the Immunochemistry and Clinical Chemistry / Specific Protein Common Reagents before being used.

Procedure for Connecting the Waste Discharge Tank

The Waste Discharge Tank is placed in its housing located on the right side of the instrument (see Fig. 3.2).

It is connected by way of the discharge pipe and electrical level probe connector. This probe is programmed to activate when a maximum volume of 1.7L is reached.

Free space of at least 50 cm on the right side of the instrument is required to access the waste tank.



Fig. 3.2

Procedure for connecting the Common Reagent bottles

The ECLECTICA™ instrument has 4 connection systems for the following 4 bottles:

- bottle containing the systemic wash solution
- brown bottle containing the substrate
- white bottle containing the stop solution
- bottle containing the IA wash solution

Each connection system is composed of:

- A cap with a collar of the same colour as the bottle to which it is to be connected.
- A mount to which the Teflon/silicon fluid hose connects.
- A level probe connected to the instrument with an electrical connector (only for connection to the Immunochemistry and systemic wash solution bottles).

The bottles containing the Common Reagents must be installed in their sliding drawer on the right side of the instrument next to the waste tank housing as shown in the following figure (Fig. 3.3).

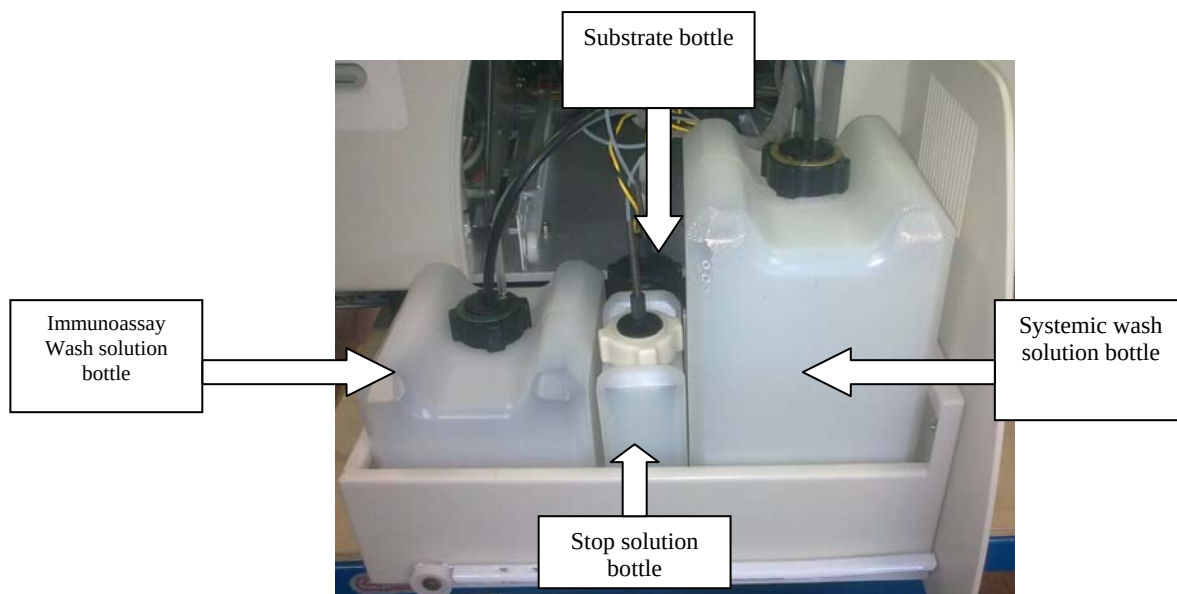


Fig. 3.3

To install the bottles containing the Common Reagents, remove their caps and completely remove their aluminium foil covers.

Connect each bottle to the instrument ring nut cap of the corresponding colour:

- Yellow ring nut cap for the bottle of Systemic Wash Solution.
- White ring nut cap for the bottle of Stop Solution (white bottle).
- Black ring nut cap for the bottle of Substrate (brown bottle).
- Green ring nut cap for the bottle of Wash Solution for IA.

First Start Up

- Launch the software as described in the paragraph: "Switching on the instrument and launching the software" in Section 7: "**Operation**".
- Fit the Reaction Segments as described in the paragraph "Change Reaction Segments" in Section 8: "**Maintenance**".
- Run washes with the *cleaning Kit* as described in the paragraph "*Wash with Cleaning Kit*" in Section 8: "**Maintenance**".
- Now load the Common Reagents as described in the paragraph "Common Reagent replacement" in Section 8: "**Maintenance**".
- Execute the **Start Up Procedure** as described in Section 8: "**Maintenance**".

OPERATING PRINCIPLES

Principle of immunoenzymatic assays

The large surface area of the magnetic particles provides both high sensitivity and a wide range of linearity.

Direct Immunoenzymetric Assay (IEMA) Phases 1 and 2

Phase 1. Immunochemical reaction

In this method (see Fig. 4.1- **Immunological reaction in the IEMA assay**), the immunological reagent is composed of a mixture of two antibodies: one conjugated with FITC (Ab1-FITC) and the other with the enzyme ALP (Ab2-ALP). During primary incubation, the two conjugated antibodies bind simultaneously to the analyte in two different positions. The concentration of immune complexes is directly proportional to the concentration of analyte present in the sample: the higher the concentration of analyte, the higher the quantity of Ab2-ALP bound in the immune complex FITC-Ab1: Ag: Ab2-ALP.

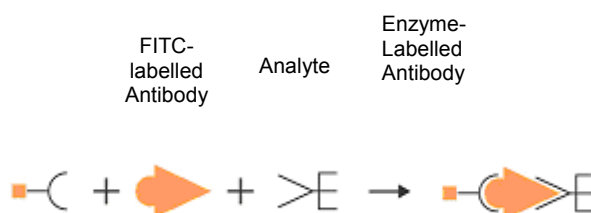


Fig. 4.1- Immunological reaction in the IEMA assay

Phase 2. Magnetic separation

At the end of the primary immunological reaction, an excess of an anti-fluorescein antibody bound to a magnetic particle is added. This binds rapidly and specifically to the immune complex Analyte-Antibodies (Ab1-FITC: Ag: Ab2-ALP) and to the antibody labelled with excess and free FITC. These are sedimented with a magnetic field (see Fig. 4.2 - **Separation in the IEMA assay**). The quantity of enzyme bound to the magnetic particles is directly proportional to the quantity of analyte originally present in the sample. The excess antibody, labelled with the enzyme, remains in solution and is eliminated by aspiration and washing.

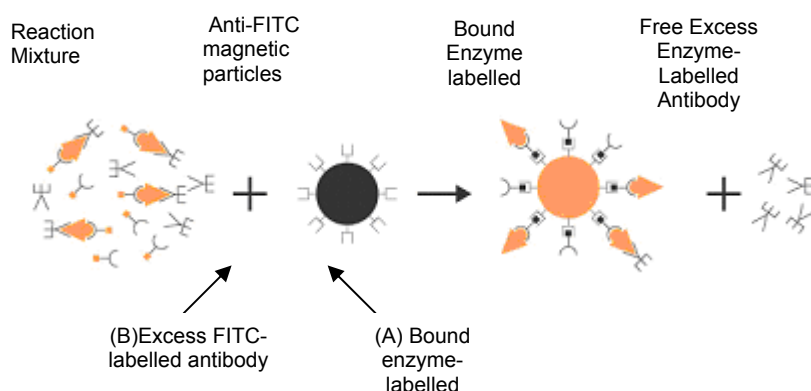


Fig. 4.2 - Separation in the IEMA assay

Competitive Immunoenzymatic Assay (EIA) – Phases 1 and 2

Phase 1. Immunological reaction

The immunological reaction of a competitive EIA assay uses a single antibody which, labelled with the enzyme alkaline phosphatase, binds the analyte to be assayed, thus forming an immune complex.

At the same time, an analogue of the analyte to be assayed is added which competes for the same sites of the antibody. This, called the labelled analyte, is conjugated with FITC.

The labelled analyte competes with the analyte in the sample for a limited number of sites on the added antibody.

A displacing agent can be added to free the analyte from the transport protein so as to enable it to react with the antibody. At equilibrium, the quantity of analyte in the sample and the quantity of bound labelled analyte are inversely proportional to each other.

Low concentration samples: the lower the concentration of analyte in the sample, the greater the quantity of labelled analyte bound to the antibody marked with the enzyme (Fig. 4.3- **Competitive EIA immunological reaction – Low concentration sample**).

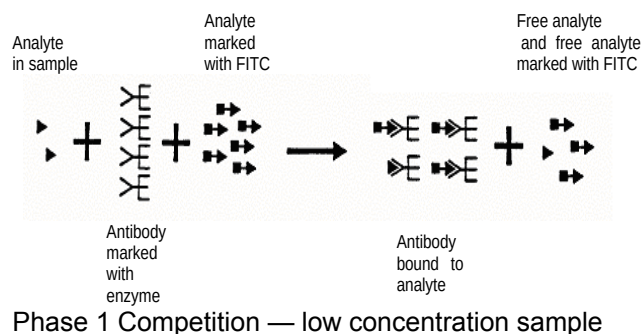


Fig. 4.3- Competitive EIA immunological reaction – Low concentration sample

High concentration samples: The higher the concentration of analyte in the sample, the smaller the amount of marked analyte which binds to the antibody marked with the enzyme (Fig. 4.4- **Competitive EIA immunological reaction – High concentration sample**).

In some assays the reaction is exchanged, since the antibody is marked with FITC and the analyte is conjugated with the alkaline phosphatase.

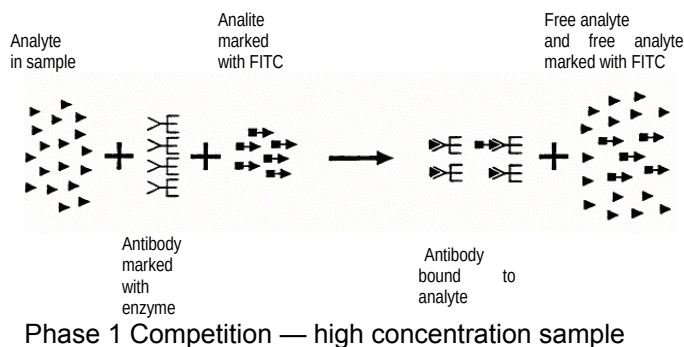


Fig. 4.4- Competitive EIA immunological reaction – High concentration sample

Phase 2. Magnetic separation

At the end of the primary immunological reaction, an excess of an anti-fluorescein antibody bound to magnetic particles is added, which binds rapidly and specifically, to the immune complex formed of the analyte marked with FITC, the antibody labelled with the enzyme (FITC-Ag: Ab-ALP) and the analyte labelled with excess and free FITC (Fig. 4. 5- **EIA Immunological Reaction Phase 2 – Low concentration sample** and Fig. 4. 6- **EIA Immunological Reaction Phase 2 – High concentration sample**). These are sedimented with a magnetic field. The quantity of enzyme bound to the magnetic particles is inversely proportional to the quantity of analyte originally present in the sample. The excess analyte and the analyte-antibody immune complex, labelled with the enzyme, remaining in solution are eliminated by aspiration and washing.

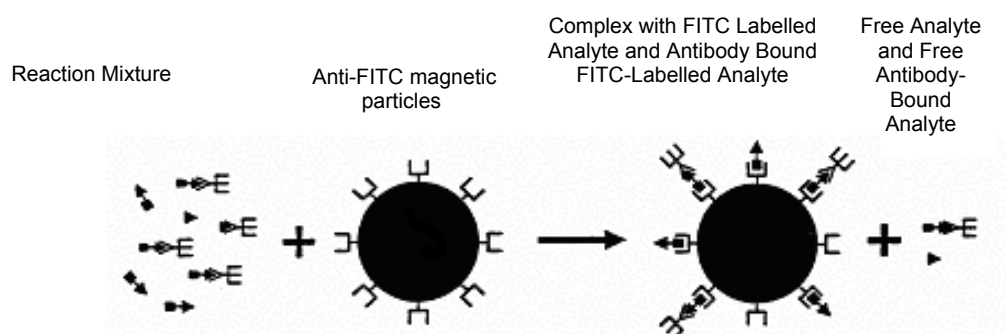


Fig. 4. 5- EIA Immunological Reaction Phase 2 – Low concentration sample

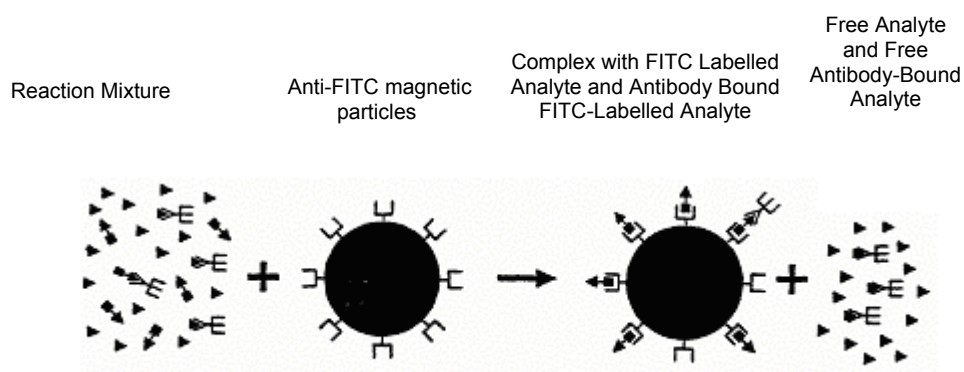


Fig. 4. 6- EIA Immunological Reaction Phase 2 – High concentration sample

Washing and separation

In both the IEMA and EIA methods the particles sediment and are separated out by a powerful magnet. The complexes bound to the magnetic particles, are then washed to eliminate excess reagent.

Phase 3. Enzymatic reaction

Once the magnetic particles have been washed, an enzymatic substrate is added to the reaction, phenolphthalein monophosphate, which results in a resuspension of the particles and initiates the enzymatic reaction.

The enzyme alkaline phosphatase in the immune complex bound to the magnetic particles removes the phosphate group of the substrate thus producing phenolphthalein in direct proportion to the quantity of enzyme present.

Colour development

On completion of incubation, the enzymatic reaction is stopped by adding a Stop Solution which turns the phenolphthalein pink.

The intensity of the colour is directly proportional to the concentration of analyte present in the sample in the IEMA method and inversely proportional to it in the IEA method.

In IEMA methods, a stronger colour indicates a higher concentration of analyte in the sample.

In IEA methods, a stronger colour indicates a lower concentration of analyte in the sample.

Colour measurement

Once the stop solution has been added and the colour developed, the magnetic particles are sedimented with a powerful magnet at the side of the reaction Cell. The clear coloured solution is ready for aspiration into the flow microcell for photometric reading of the base wavelength of 546 nm at which the phenolphthalein (Fig. 4. 7- **Phenolphthalein absorption spectrum**) has maximum absorption and at the wavelength of 492 nm where the absorption is around a quarter of that at the base wavelength.

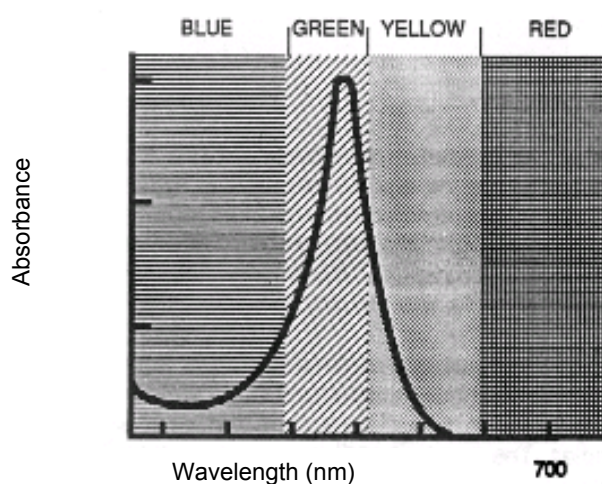


Fig. 4. 7- Phenolphthalein absorption spectrum

The base measurement at 546 nm yields a high sensitivity, thus revealing even minimal amounts of the target analyte.

Some concentrations of analyte produce such a strong colour that they cannot be measured directly at this wavelength. Such solutions can be measured accurately at 492 nm.

The data processing system of the ECLECTICA™ instrument enables measurements to be made at both wavelengths.

Spectrophotometric Reading System

A spectrophotometer carries out the spectrophotometric reading.

The spectrophotometer is provided with a halogen lamp whose light passes through one of the 9 interference filters, which can be selected using an internal microprocessor.

The measurement chain is shown in the following diagram (Fig. 4.8).

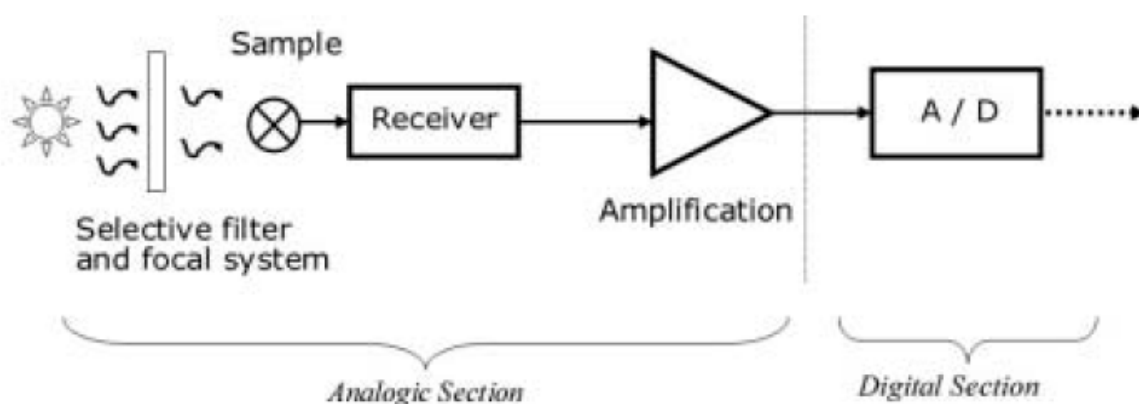


Fig. 4.8

Data processing and results

Standardization

The colour absorption is proportional to the concentration of substance available to react in the antigen-antibody reaction (Fig. 4.9 - **Concentration vs. signal**).

Comparing the absorption with that produced by a known amount of the substance in question allows us to determine its concentration in the sample.

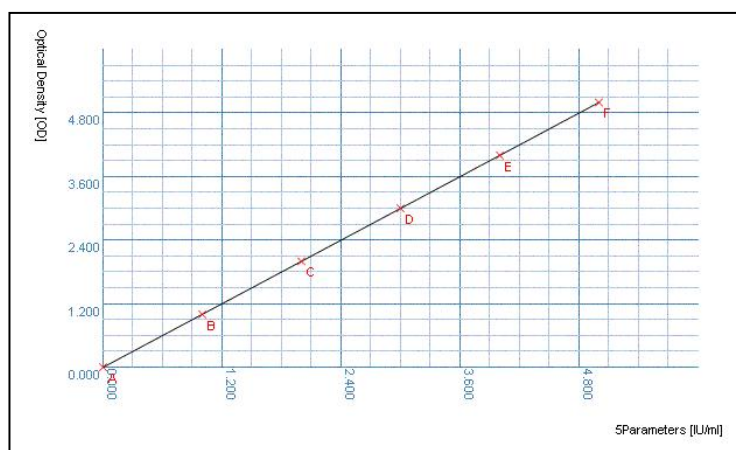


Fig. 4.9 - Concentration vs. signal

A series of known concentrations are assayed with the same technique to determine the relation between a given concentration and the resulting colour. This relation is called the standard curve. Sample standard curves for the IEMA and EIA methods are given in the figures Fig. 4.10 - **Sample IEMA standard curve**, and Fig. 4.11 – **Sample EIA standard curve**. The procedures for obtaining the standardization are given in Section 7 “Operation”.

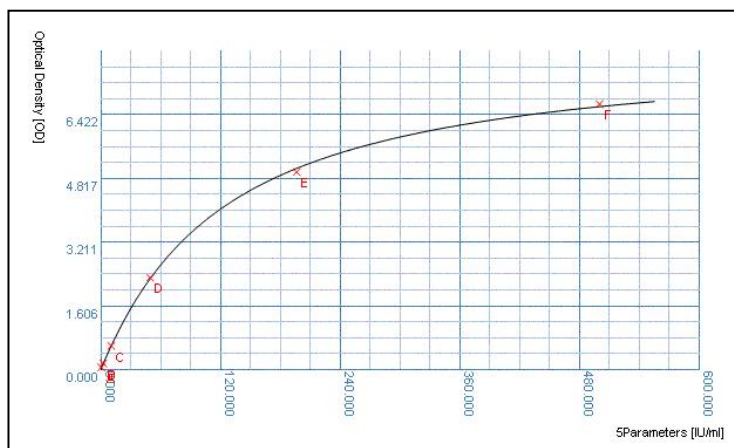


Fig. 4.10 - Sample IEMA standard curve.

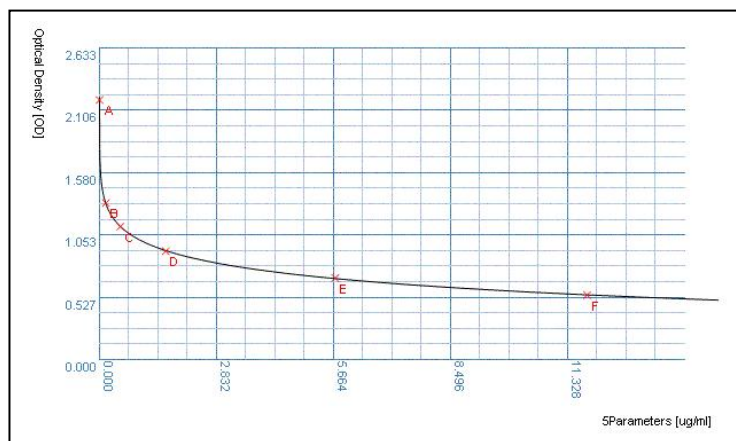


Fig. 4.11- Sample EIA standard curve.

The curve generated by the ECLECTICA™ instrument during standardisation is defined by a mathematical relationship. This can be either 5-parametric or 4-parametric (Fig. 4.12 **5-Parameter equation** and Fig. 4.13 **4-Parameter equation**).

These equations relate the concentration of the analyte (x) with the colour or absorbance on completion of the reaction (y).

The 5 parameter equation contains 5 factors which are constant for each lot of reagent:

$$y = \frac{a - d}{\left[1 + e^{\frac{b}{s}(\ln x - c)} \right]^s} + d$$

Fig. 4.12 5-Parameter equation

Parameter a: The upper asymptote is the maximum colour density. In an IEMA method, this corresponds to a high concentration of analyte; in an EIA method, to a low concentration (lack of competition).

Parameter b: The slope of the straight section on the logit-log transform. In other words, the slope of the curve.

Parameter c: The intercept of the logit-log transform (horizontal displacement of the curve), in other words, the position of the median point relative to the concentration of analyte.

Parameter d: The lower asymptote is the minimum colour density. In an IEMA method, this corresponds to a blank or base measurement without analyte; in an EIA method, it corresponds to the analyte's saturation point.

Parameter s: the asymmetry of the curve. This parameter is typically set to 1, when the curve assumes a perfectly symmetrical S.

The 4 parameter equation contains 4 factors which are constant for each lot of reagent:

$$y = \frac{a - d}{1 + (x/c)^b} + d$$

Fig. 4.13 4-Parameter equation

Parameter a: the expected response for a zero assay,

parameter b: the slope of the logit/log relation (multiplied by -1),

Parameter c: indicates the assay corresponding to the expected response halfway between “a” and “d”,

Parameter d: corresponds to the expected response for an infinite assay.

Immunology calibration method

The ECLECTICA™ calibration uses a master curve and a two point verification procedure.

Master curve

The master curve is calculated from a number of calibration curves derived from different instruments.

The parameters for the curve are stored on the Smart Card supplied with each pack of Specific Reagents.

The number of master curve calibrators depends on the analyte in question (see the User Instructions of each single assay). The calculation method used for processing the data includes the two previously described mathematical models: 4- and 5-parameter.

The design of the ECLECTICA™ instrument and the stability of its reagents make it unnecessary to run a daily curve. The characteristics of the instrument which make the creation of a daily curve unnecessary are the following:

- repeatable dispensing
- precision timing
- accurate temperature control
- stability of reagents

Instead of analyzing all the calibrators to register a curve (standard calibration), the user need only load the Smart Card, supplied with the package of Specific Reagents, into the system.

The master curve cannot be used as it is to evaluate samples: it becomes suitable for this only after the 2-points verification. (see below)

Two-point verification

The master curve enables the user to register a curve which, while specific to the assay in question, is not necessarily suited to the characteristics of the system. The user must therefore analyse the two Controls supplied with each pack of Specific Reagents: Control 1 (C1) and Control 2 (C2). The two Controls, once run, will yield absorbance for comparison with the reference values on the instrument.

Valid Curve

If the verification run with the two Controls conforms to all acceptability criteria, the calibration curve is classified as valid for the current batch of Specific Reagent.

Frequency of verification with the two Controls

The Eclectica™ system requires verification of the calibration for each assay whenever:

- The calibration verification deadline expires (the period of validity of the calibration is analyte-dependent, ranging from 2 to 4 weeks; refer to the assay User Instructions for further information).
- The Specific Reagent lot number changes.
- The Common Reagent lot number changes.
- The Quality Control serum values are out of tolerance.
- The instrument is serviced.

Standard calibration (standardization)

If necessary, the user may run a standard calibration of the system using the calibrators supplied in the Calibration Kit. The IA standardization, once performed, does not require to be validated through C1 and C2 until the expiry date of the standardization itself (2-4 weeks, analyte dependant).

Principle of Clinical Chemistry Assays

Clinical Chemistry Determinations

Clinical Chemistry or Clinical Biochemistry are generic terms which commonly cover the majority of quantitative analyses of human fluids based on chemical or biochemical methods. It is one of the three major disciplines applied in medical laboratory work, along with Haematology and Microbiology.

The biological fluids on which measurements are made are serum, plasma, urine, cerebrospinal fluid; in exceptional cases, pleural, pericardial and peritoneal or synovial fluids may be used.

In Clinical Chemistry three major groups of analytes are measured:

- **Substrates:** Glucose, Nitrogen, Cholesterol, etc.
These are known molecules which upon addition of the reagents produces a measurable colour. Their concentration is represented by the ratio of the colour developed by the sample to that obtained from the reference standard.
- **Enzymes:** GOT (AST), GPT (ALT), CPK, etc.
These are molecules which act on the reagent and vary its extinction value. The delta extinction, measured over a standard period of time, is proportional to the concentration.
It is usually read in UV at 340/365 nm because the ΔE is obtained from the action of the enzyme on a NAD^+ -NADH system.
- **Electrolytes:** The most common method used for these measurements is spectrophotometry.

Types of reaction

The chemical reactions can be classified into three main groups:

- End - Point
- Kinetic
- Fixed-Time.

End-Point reactions

End-Point reactions (Fig. 4.14- **End Point reaction – single reagent**) are the classical reactions used to measure the concentration of substrates. They can be enzymatic reactions in equilibrium due to the complete exhaustion of the analyte (e.g. formation of a complex of the analyte with a specific kelating substance).

Calculation: Reading in the visible spectrum after termination of the reaction with production of stable colour.

The reaction may involve one or two reagents.

Example:

$$\text{Concentration of calcium in the sample (mg/dL)} = \frac{\text{OD SAMPLE}}{\text{OD STANDARD}} \times \text{Standard Concentration (mg/dL)}$$

where:

OD SAMPLE = optical density of sample
 OD STANDARD = optical density of standard
 Standard concentration = known concentration of reference standard

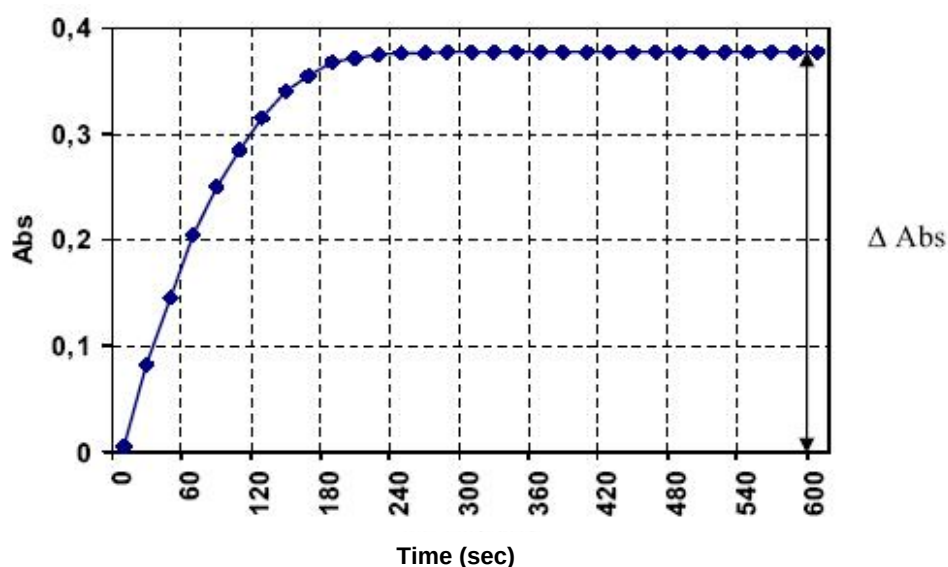


Fig. 4.14- End Point reaction – single reagent

The above graph (Fig. 4.14- **End-Point reaction – two reagents**) shows a typical End Point reaction: after a certain period of time (depending on the concentration of the enzyme, the temperature, the type of reagent, etc.) the reaction reaches equilibrium and the colour remains stable for a variable period of time (minutes to hours).

There are two types of End Point reaction: single reagent (Fig. 4.14- **End-Point reaction – two reagents**) or two (or three or more) reagents

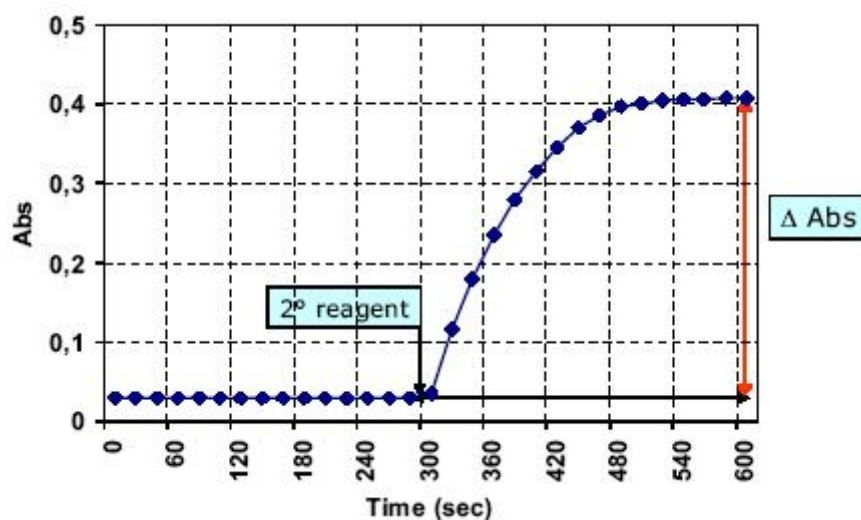


Fig. 4.15 - End-Point reaction – two reagents

Kinetic reactions

This type of reaction is generally used to measure the catalytic activity of enzymes.

Calculation:

Reading in UV at fixed, well-defined intervals of time. The resulting ΔE is multiplied by the specific factor for the analyte in question.

$$\frac{\Delta A / \text{min} \times V_T \times 1000}{e \times d \times V_c} = \frac{A / \text{min} \times 2,200 \times 1000}{6,22 \times 1 \times 0,200} = \Delta A / \text{min} \times 17680$$

Example:

U/L = AST activity in international units per litre.

$\Delta A / \text{min}$ = Diminution in absorbance per minute (mean of three readings).

V_T = Total reaction volume

1000 = Conversion into litres of volumes

e = Micromolar extinction coefficient of NADH^+H^+
(6,22 $\text{cm}^2/\mu\text{mole}$ at 340 nm)

d = optical range (1 cm.)

V_c = Volume of sample in final reaction mixture.

Kinetic reactions can also involve one or two reagents (see Fig. 4.16 - Kinetic reaction – Single Reagent and Fig. 4.17 Kinetic reaction – Two Reagents).

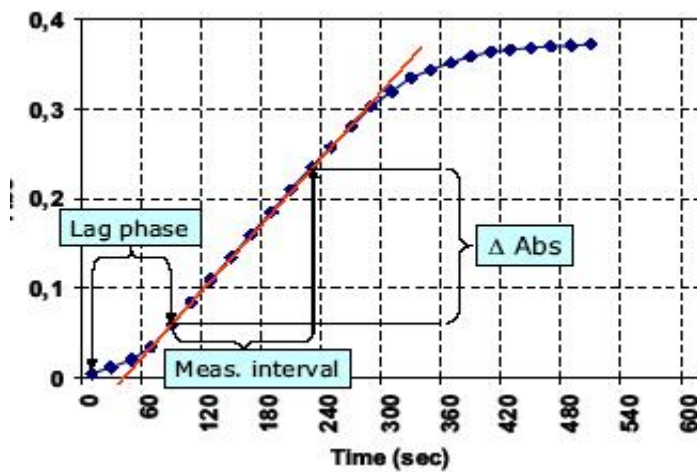


Fig. 4.16 - Kinetic reaction – Single Reagent.

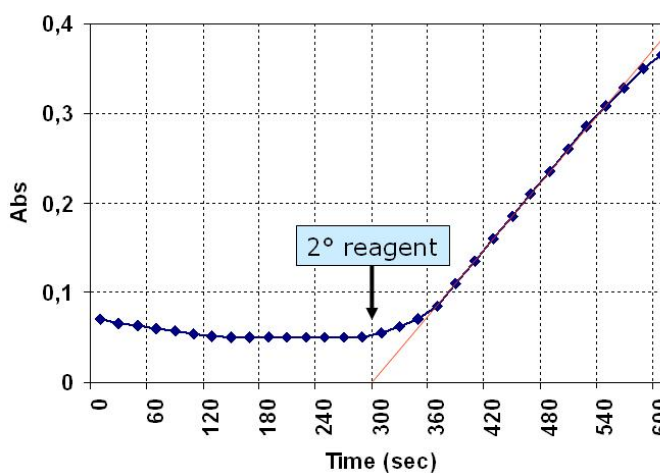


Fig. 4.17 - Kinetic reaction – Two Reagents

Fixed-Time

This type of reaction is generally used in enzymatic and chemical reactions and measures the variation of absorbance over a set time.

The variation of absorbance over a set time is not generally linear.

Calculation: After reading in the visible spectrum after a set time for both the sample and the standard.

Example:

$$\text{Concentration of Creatinin in the sample (mg/dL)} = \frac{\Delta A/\text{min sample}}{\Delta A/\text{min standard}} \times \text{Standard Concentration of Creatinin (mg/dL)}$$



WARNING: Refer to the User instructions given in the “Application Protocols Manual” (p/n: ECLP4050000018) for further information on Clinical Chemistry assays.

SECTION 5

FUNCTIONS

Purpose

ECLECTICA™ (

Fig. 5.1) is a closed system that uses dedicated reagents. The assays that can be run automatically with the ECLECTICA™ instrument are described in the “ECLECTICA™ Assay Manual” (code: ECLP4050000018).

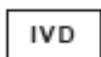
The ECLECTICA™ instrument automatically performs all assay operations except for preparation of the samples.



Fig. 5.1



WARNING: In some countries, use of the instrument may require, for running certain of the assays for which it is designed, the approval of or registration with Governmental Agencies



The ECLECTICA™ system is intended for use in in vitro diagnostics

Description of functions

The ECLECTICA™ instrument provides the following functions, as given in the Application Protocols for the assays:

- Sampling of the biological samples
- Sampling of the Reagents
- Incubation (at 37°C)
- Magnetic separation
- Wash (after separation)
- Photometric reading
- Processing and printout of the results

The ECLECTICA™ system has the following characteristics:

HARDWARE

The system has the following principal functions:

- It enables positive identification of the samples and reagents by reading their barcodes.
- It determines the presence of the samples/reagents to be dispensed by means of a level sensor.
- It dispenses the samples.
- It enables easy loading by Smart Card of the information regarding the lot of reagents used on the instrument.
- It quickly reads the absorbance by means of a photometry station.

SOFTWARE

The software consists of an easy to use management system that enables interactive communication between user and instrument.

Additional software characteristics are:

- Easy access to the menus through the interface with Touch Screen.
- Easy step-by-step programming.
- Processing and printout of the results.

CONSUMABLE MATERIALS

All Consumable Materials (see the list in Section 3: “**Consumables/disposable materials**”), except for the Reaction Segments, diuents and wash solutions, come with Smart Cards that allow the test data/specific lots to be automatically loaded.

All of the bottles containing the Specific Reagents, Controls, Calibrators and Diluents have barcodes so they can be positively recognised once loaded on the instrument.

Description of subsystems

The ECLECTICA™ instrument consists of the following functional subsystems:

- Work Area
- Barcode reader identification system
- Sampling, Specific Reagent, Control, Calibrator, Diluents and Separation Reagent system
- Magnetic Separation System
- Reaction cuvettes wash system
- Common Reagents sampling system
- Reading system
- Management Software.

These subsystems are described in the following paragraphs.

Work Area

The area contains:

- Reagents dish,
- Samples carousel,
- Reaction Segments Section and Incubation System.

Reagents Dish

This dish (Fig. 5.2), located on the left side of the Work Area, is divided into two crowns, both refrigerated with Pelletier effect and numbered counter-clockwise with:

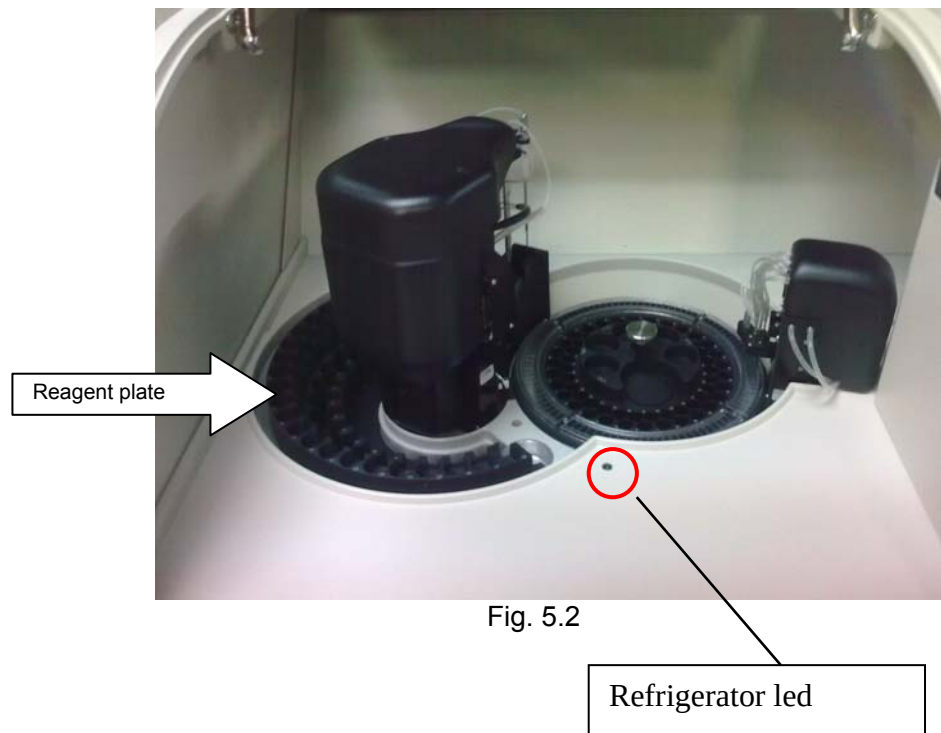
- 28 positions to house Calibrators and Immunochemistry Controls (outer crown)
- 20 positions for Immunochemistry and Clinical Chemistry Specific Reagents (inner crown).
- 1 position for the Clinical Chemistry diluent.

Each position is identified by a milled number that follows the housing it refers to clockwise.

The refrigeration system is controlled by the switch on the rear of the instrument (see Section 7 "**Operation**").

This system keeps the temperature around 15°C below ambient temperature.

NOTE: The instrument is now equipped with a refrigeration system ON led (Fig. 5.2). Make sure that the refrigerator is ON (green led) if the reagents are left onboard the instrument.



Samples Carousel

The samples carousel (Fig. 5.3) is on the right of the instrument's Work Area. Standard installation envisages a samples carousel with 60 positions able to house test tubes of size 12x (50 mm - 100 mm).

Each carousel numbers the samples in a counter-clockwise sequence in two rows: from 1 to 30 and from 31 to 60 for the 60-position dish. The identifying numbers are silk screened on.

Each number is printed in advance of its respective position.

The positions, which are user-programmable, can also be used for Clinical Chemistry calibrators.



Fig. 5.3

The samples carousel also features:

- 5 positions for the Diluent bottles used on the ECLECTICA™ system for immunochemistry assays.
- One position for the Separation Agent container.

Incubation System

The incubation system is made up of an independent rotor coaxial to the samples carousel containing the housings for four Reaction Segments (Cells), each consisting of 24 cuvettes (Fig. 5.4). The rotor thus has 96 positions and allows for replacing and loading the 4 Reaction Segments on request. The 96 Cells are disposable: the software ensures that the reaction Cells are used once only.

The instrument uses the first four cuvettes of the first segment to wash the reading Cells during the after each spectro-photometric reading.

The incubation temperature is monitored and kept to a range of $37^{\circ} \pm 1$ C.

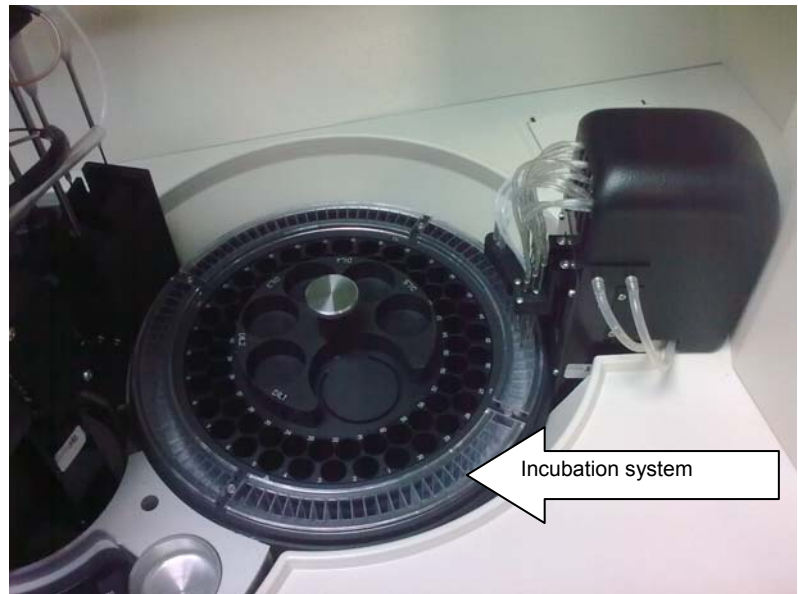


Fig. 5.4

Barcode reader identification system

The identification system is composed of a barcode reader mounted to the sampler arm which positions it to read the label barcodes.

The barcode reader (

Fig. 5.5) serves to positively identify bottles of Specific Reagents, Controls, Calibrators and samples (primary test tubes with barcodes).

The reader is able to read various types of barcodes (see Section 10, “**Technical Specifications**”).

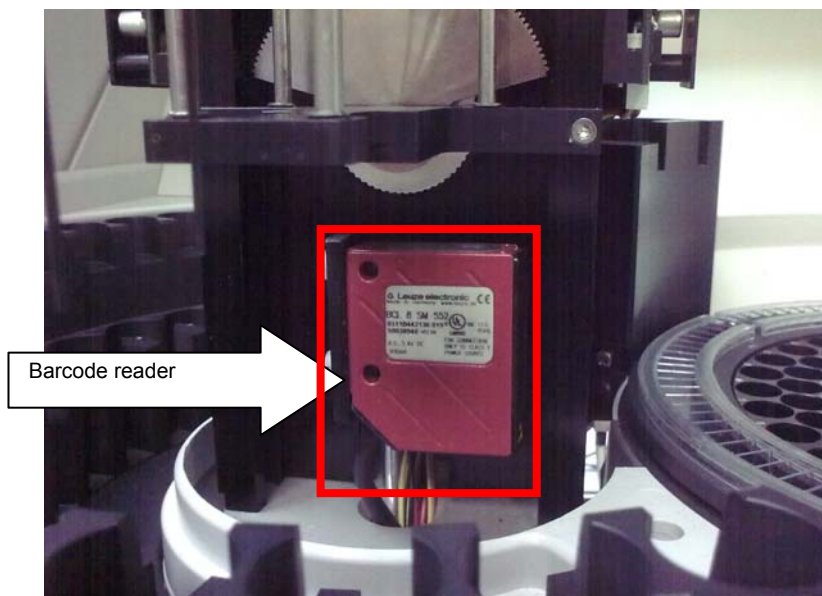


Fig. 5.5

Sampling System

The system for sampling Samples, Specific Reagents, Controls, Calibrators, Diluents and Separation Solutions is composed of:

- 2 Sampling Needles
- Syringe
- Peristaltic pump
- Needle wash station.

Sampling Needles

The sampling needles SN1 and SN2 (Fig. 5.6). aspirate and dispense respectively:

- Samples, Immunochemistry Controls and Calibrators, Diluents and Separation solution (Common Reagent) (outer needle SN1);
- Specific Reagents, diluents, samples and Clinical Chemistry calibrators (inner needle SN2).

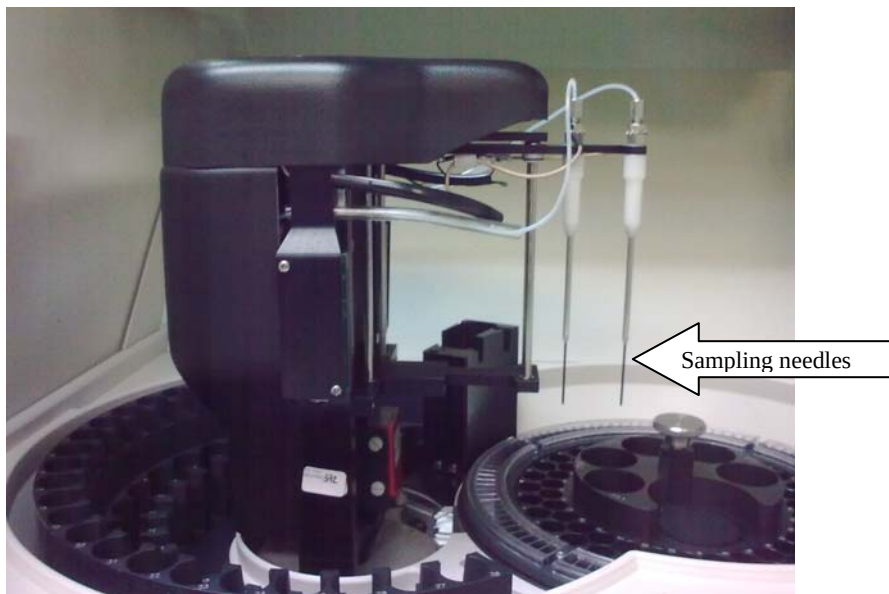


Fig. 5.6

Each needle has an electronic level sensor so as to minimize the depth of penetration of the needle into the liquid, and recognises the presence of adequate volume.

Each needle is washed inside and out in a specific wash trap with the specific wash solution for the purpose of reducing carry-over phenomena.

Syringe

The syringe is assembled in the pump compartment on the right side of the instrument, behind the Waste Discharge Tank.

The syringe has a capacity of 1mL. It handles all precision, aspiration and dispensing functions for the sampling system.

It draws and dispenses samples, Specific Reagents, Controls, Calibrators, Diluents and Separation Solution (Common Reagent).

When a given volume has been dispensed and before the next draw cycle, the syringe's integral solenoid valve is switched to deliver wash solution to the sampling needles (peristaltic pump delivery).

Peristaltic pump

The peristaltic pump is mounted in the pump compartment on the right side of the instrument.

It washes the sampling circuits. The wash cycles are predefined in such a way as to reduce contamination.

Needle wash station

The wash station (Fig. 5.7) consists of 2 wash traps (one for each needle) and a wash liquid waste collection duct. It is located between the reagents dish and the samples carousel.

The sampling needles are washed inside and out in their wash traps after every dispensing cycle. The wash solution is delivered to the needles by the peristaltic pump.

The used wash solution is sent to the Waste Discharge Tank by a second peristaltic pump.



Fig. 5.7

Magnetic Separation System

The magnetic separation system is composed of a permanent magnet located underneath the wash station on the right side of the instrument.

The magnetic separation system separates the immunocomplex that has formed as a consequence of the reaction from any excess free reagent.

The separation is achieved by approaching the magnet to the reaction Cells, thus attracting the separation agent's magnetic particles to the lower exterior Section of the reaction Cell itself.

The liquid freed of magnetic particles can then be drawn up during the wash and spectro-photometric reading cycles.

Reaction cuvettes wash system

The reaction cuvette wash system is composed of:

- A manifold (Fig. 5.8) comprising 12 needles (4 dispensing needles and 8 aspiration needles)

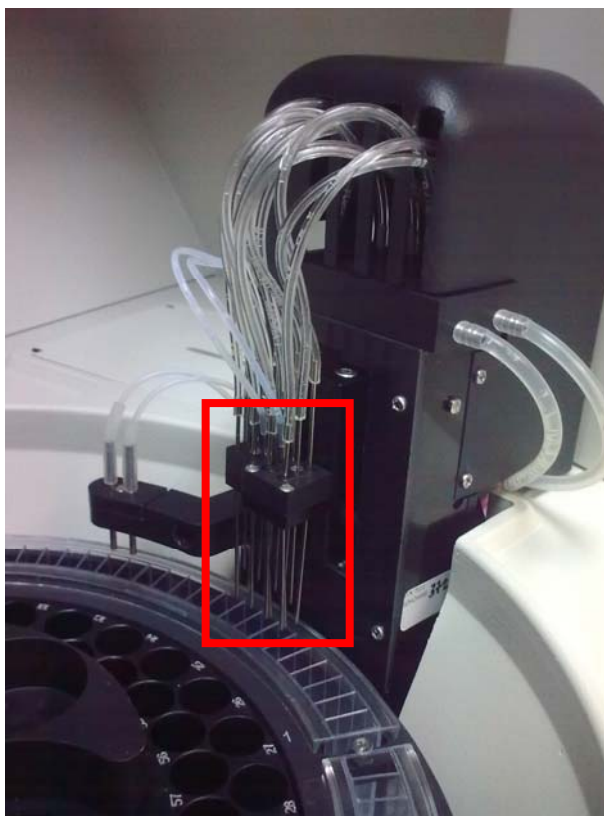


Fig. 5.8

The system runs the wash cycle after magnetic separation by injecting the Wash Solution into the reaction cuvettes via the 4 dispensing needles. The reaction mixture is then drawn up from the four cuvettes. Then the Wash Solution is once again dispensed into every Cell and the magnetic particles are returned to suspension by means of rapid agitation. At this point the instrument performs a new magnetic separation and Wash Solution dispensing cycle. The reaction mixture is then drawn up anew.

Common Reagents sampling system

The immunochemistry Common Reagents sampling system (Substrate and Stop) is composed of two needles (one for each reagent) located to the left of the Wash System manifold (Fig. 5.9) in the reaction Cells, and two pumps (one for each reagent).



Fig. 5.9

At the end of the wash, the Common Reagents (Substrate and Stop) are dispensed for enzymatic/colorimetry development. The pumps draw the Common Reagents and dispense them into the reaction cuvettes with the sampling needles.

Reading system

The reading system is composed of:

- Needles for drawing up the solutions into the flow Cells located in front of the wash system manifold in the reaction Cells (
- Fig. 5.10).

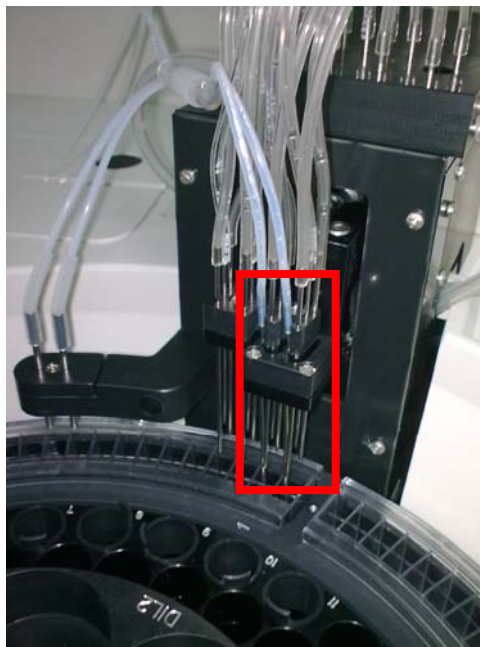


Fig. 5.10

- Two peristaltic pumps,
- Two flow Cells located in a housing to the right of the samples carousel (
- Fig. 5.11)
- A spectrophotometer: the light emitted by the halogen lamp passes through interference filters mounted on a wheel, which is microprocessor controlled to select the filter to match the type of reading required by the method in question (the specifications of the filters are given in Section 10 "**Technical Specifications**").

The solution to be measured is drawn up for spectrophotometry by the peristaltic pumps into the flow Cells and then discharged into the waste tank.

The flow Cells are washed after each reading with wash solution, which is dispensed into the first four cuvettes of the first Reaction Segment.



Fig. 5.11

Management Software

The software of the ECLECTICA™ instrument works with the Windows XP Home Edition operating system.

Its multitasking structure allows the user to move from one menu to another to monitor the instrument's operation and status without interfering with any processes that may be in progress.

SECTION 6

RESTRICTIONS

This Section describes the restrictions to be observed when running assays with the ECLECTICA™ system.

The ECLECTICA™ system (instrument and consumables) is intended exclusively for in vitro diagnostic use.

The ECLECTICA™ system (instrument and consumable materials) is designed for professional applications. It must therefore be used only by expert laboratory personnel.

The user must strictly observe all information contained in this Section.

Restrictions on immunoenzymatic assays

Do not use either EDTA or sodium citrate as an anticoagulant because they prohibit enzymatic reaction.

Cloudiness, aggregates or precipitates that may be present in the reagents may be a sign that they have possibly deteriorated; in this case notify the local dealer, reporting the problems noticed.

As is true for all immunoenzymatic assays, results may be influenced by factors present in the patient's serum. Although formulation of the reagents was studied in order to minimize interference due to the presence of both heterophile antibodies and a specific bonds, possible invalidation of a single sample cannot be ruled out as is true for all "Sandwich" systems. For diagnostic purposes, the results obtained from this assay must always be used together with the clinical examination, the patient's anamnesis and other laboratory investigations.

Scrupulously follow the User Instructions because any modification can bring about a change in the results.

The use of reagents, consumable material or spare parts not supplied by the authorised dealer may bring about incorrect results.

Patients undergoing treatment with monoclonal antibodies (Mouse), whether for diagnostic or therapeutic purposes, may have developed anti-mouse antibodies (HAMA). The presence of HAMA in the sample may generate both false positive (high) and negative (low) values in systems using monoclonal antibodies. Samples containing HAMA coming from these patients should not be assayed in the ECLECTICA™ system.

Interpreting the assay results

For diagnostic purposes, the results obtained from each assay must always be used in combination with the clinical examination, the patient's anamnesis and other laboratory investigations.

SECTION 7

OPERATION

Preparation for operation

The information necessary for using the ECLECTICA™ instrument correctly is given in the following paragraphs.

NOTE: the information regarding handling the Consumable Materials is general; it is therefore advisable to read the instructions contained in the "ECLECTICA™ Assay Manual" (code: ECLP4050000018).

Safety Recommendations

Carefully read Section 1, "Safety", and Section 6: "Operating Precautions" and follow the rules therein in order to reduce risks relating to use of the instrument.

Personnel assigned to operating the instrument must have good familiarity with the good laboratory practices (GLP), particularly with reference to In-Vitro analyses (IVD).



WARNING: As well as having a detailed knowledge of this manual, the user must attend a specific course authorised by the manufacturer, Adaltis Srl.

Samples

Carefully read the information given hereunder and the more specific information contained in the "ECLECTICA™ Assay Manual" (code: ECLP4050000018) referring to the analytes to be assayed for correct utilisation of the samples.

Type of Samples

The samples that can be used with the ECLECTICA™ instrument are serum, plasma, urine or other biological fluids (carefully read the section concerning every assay given in the "ECLECTICA™ Assay Manual", code ECLP4050000018).

Preparing the Samples

Before being used, the samples must be taken to ambient temperature. Moreover, they must be free of particles, suspensions, filaments, clots, fibrin, foam or bubbles that could make their dispensation difficult.

NOTE: The information given in this manual regarding the samples is general. It is therefore advisable to read the instructions for use contained in the "ECLECTICA™ Assay Manual" (code: ECLP4050000018).



WARNING: Incorrect preparation of the samples may produce inaccurate and unreliable results.

Storing the samples

In order to prevent alteration of the samples, store them according to the specifications provided in the instructions contained in the "ECLECTICA™ Kit Assay Manual" (code: ECLP4050000018).

Identifying the Samples

The ECLECTICA™ instrument is supplied with a barcode reader that enables positive identification of samples contained in primary test tubes provided with barcode labels.

The types of barcodes compatible with the reader are given in Section 10 of this manual, "**Technical Specifications**".

If the laboratory does not use test tubes with barcodes, the instrument enables positional identification.



WARNING: The bar code label must be located in such a way that the test tube is at least 2 mm away from the edge of the samples carousel



Sample Test Tubes

Test tubes having the following characteristics must be used in order for the instrument to operate correctly:

Type 1 samples carousel60 positions

Diameter: 12/13 mm

Height: 50 - 100 mm.



WARNING: Using test tubes having specifications other than those indicated could cause problems during the sample taking/dispensation phases. Primary test tubes containing activators on gel or microparticles are advised against.

Minimum volume of the samples / standards

The assays require a specific sample volume in the range from 5µl to 10 µl of sample for each determination. This volume does not include the dead volume (unusable volume in the sample container) or the additional volume required for executing replicates or other tests to be run on the same sample.

So the minimum volume of the samples necessary for executing the assay consists of the dead volume plus the volume of sample liquid necessary for executing the analytic assays:

- dead volume is 200 µl.
- the minimum sample volume is given in the instructions for using every single analyte (see “ECLECTICA™ Kit Assay Manual”, code ECLP4050000018).
- the minimum standard volume is given in the instructions for using every single analyte (see “ECLECTICA™ Kit Assay Manual”, code ECLP4050000018).

Diluting the samples

If required by the assay, the ECLECTICA™ instrument performs pre-dilution of the samples.

Samples with concentrations higher than the analytic range can be assayed following dilution with the specific Diluent.

Automatic dilutions may be made directly by the ECLECTICA™ instrument.

The bottle of Diluent specified in the instructions for use contained in the “ECLECTICA™ Kit Assay Manual” (code: ECLP4050000018) must be

placed in the specific position on the ECLECTICA™ instrument sample carousel.

Alternatively, dilutions can be carried out manually before loading the samples onto the instrument.

Consumable Materials

The Consumable Materials required to carry out the tests for each method (determination of an analyte) are indicated in the user instructions in the "ECLECTICA™ Kit Assay Manual" (code: ECLP4050000018).

NOTE: The information regarding consumable materials given in this Manual is general. Carefully read the "ECLECTICA™ Kit Assay Manual (code: ECLP4050000018).

The following consumable materials required to execute assay can be used with the ECLECTICA™ instrument:

Common Reagents for Immunochemistry assays (reagents required to execute all the applicable assays on the instrument):

- Systemic Wash Solution, Immunoassay Washing Buffer and a pack containing one Substrate Solution, one Stop Solution, one Separation Reagent and a Smart Card. Each pack is sufficient for 200 tests.

Common Reagents for Clinical Chemistry assays:

- Systemic Wash Solution.

Specific Reagents for Immunochemistry assays (Specific Reagents for a single assay):

- A pack containing the Specific Reagents, Controls and a Smart Card. Each pack is sufficient to execute 100 tests.

Specific Reagents for Clinical Chemistry assays (Specific Reagents for a single assay):

- A pack containing the Specific Reagents and a Smart Card.

Calibration Set (Calibrators) (reagents to run calibration curves for a single Immunochemistry assay)

- A pack contains the series of calibrators (5-7) and a Smart Card.

Calibration Set (Calibrators) (reagents to run calibration curves for a single clinical chemistry)

- A pack contains the series of calibrators and a Smart Card.

Parametric Multicalibrator (Reagents for calibrating Clinical Chemistry assays):

- A pack containing the multicalibrator bottles and a Smart Card.

Diluents (reagents dedicated to groups of analytes for executing sample dilutions):

Each pack contains dilution solutions:

- Each Immunochemistry pack contains 3 bottles (3x20 ml) and a Smart Card.
- Each Clinical Chemistry pack contains 3 bottles (3x50 ml).

Reaction Segments (reaction Cells for running all the assays possible on the instrument).

- Each pack contains 100 segments.

NOTE: the bottles of Specific Reagents, Controls, Calibrators and Diluents are provided with labels showing a bar code for positive identification of the bottles on board the instrument, by reading the labels themselves with a bar code reader.

Preparing the Consumable Materials

The Common Reagents must be brought up to ambient temperature (18°C...25°C) before being loaded onto the ECLECTICA™ instrument.

The Specific Reagents, Controls and Calibrators can be loaded onto the instrument (in the refrigerated reagents dish) directly from the refrigerator.

The Diluents must be at ambient temperature (18°C...25°C) before being loaded onto the instrument.



WARNING: Specific Reagents, Controls, Calibrators and Diluents must not contain foam or bubbles on the surface or inside the liquid.

Storing the Consumable Materials

In order to prevent alteration of the Consumables, store them according to the specifications provided in the instructions contained in the "ECLECTICA™ Kit Assay Manual" (code: ECLP4050000018).

Identification

The ECLECTICA™ instrument is equipped with a barcode reader that enables positive identification of Specific Reagents/Controls/Calibrators/Diluents by way of the barcode printed on every bottle.

The barcode used for these Reagents is "code 128" (see Section 10, "Technical Specifications").

Primary functions of the OpenLAB

The following headings describe the primary functions of the OpenLAB software required to execute assays using the ECLECTICA™ analyzer.

- Turning the instrument on.
- OpenLAB Start Up
- Description of the primary functions
- Running the Start up procedure.
- Consumable Materials Loading.
- Programming a worklist
- Executing a worklist.
- Viewing and printing the results of a worklist.
- Executing the Shut Down procedure.

NOTE: when executing the operations described in the following headings, the management software can dialogue with the User by means of messages designed to assist in performing the relative operations correctly.

The meanings of the messages and any consequential procedures are described in: "Management software messages". You should therefore read this heading carefully.

Powering on the instrument

There are two switches on the rear of the instrument on the right (Fig. 7. 1):

- the lower switch powers the instrument on,
- the upper switch activates the Reagents carousel refrigeration system.

Turn on both switches and wait for the software initialisation procedure to complete.

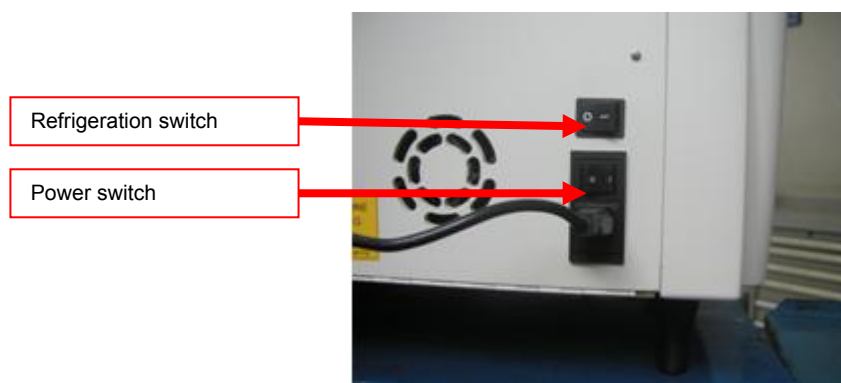


Fig. 7. 1

OpenLAB Start Up

Open the ECLECTICA™ *OpenLAB* management software by double clicking on the Eclectica OpenLAB icon on the desktop



or by clicking on Start in the Windows taskbar and selecting *All Programs-> Adaltis-> OpenLAB Start up*.

The main menu of the ECLECTICA management software will appear (Fig. 7.2 - Easy User Interface). **You can navigate around the various program modules without the modules being closed each time you switch from to another.**

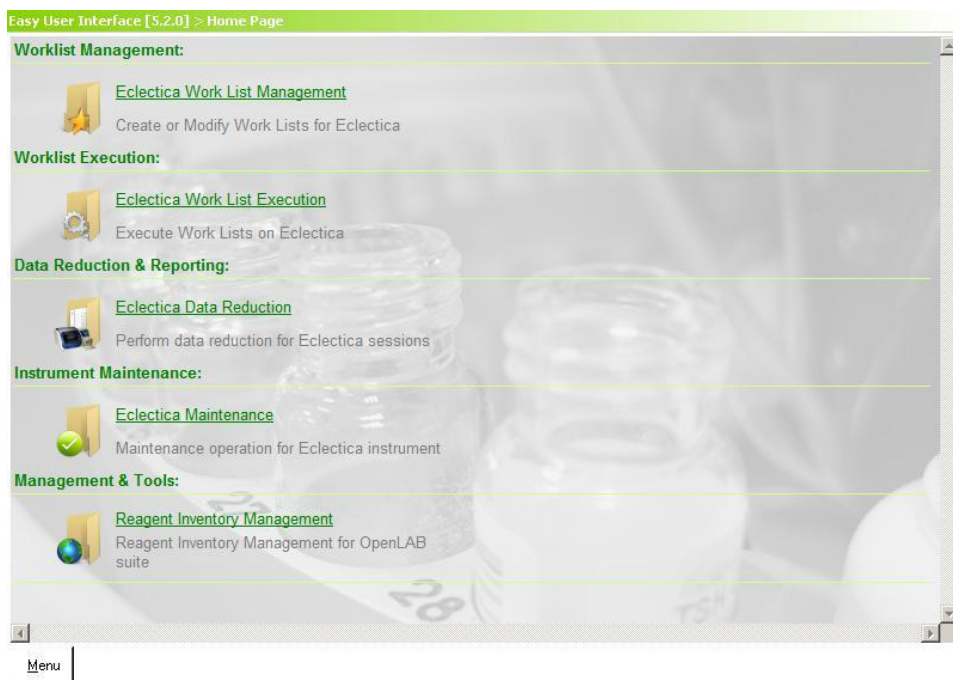


Fig. 7.2 - Easy User Interface

The **Easy User Interface** (Fig. 7.2 - Easy User Interface) allows you to:

- ❖ program a worklist
- ❖ execute a worklist
- ❖ record an executed worklist
- ❖ manage the warehouse
- ❖ perform daily/weekly maintenance activities on the instrument.

This section provides details of each of the above functions:



WARNING: The ECLECTICA™ management software is touch-screen operated and features a step-by-step help function. Consequently, you can go from one operating function to the next by means of the "Next" and "Back" buttons in the various pages.

"Next" opens the next page. "Back" opens the previous page.

Always use the stylus provided with the instrument to select the icons on the screen.

Alternatively, the trackball on the top RH side of the keyboard can be used. In this case, use the two buttons on the top LH side of the keyboard as the standard mouse left and right buttons.

Main Menu of the OpenLAB

The OpenLAB functions makes it possible to run Immunoassay, Clinical Chemistry, and Specific Protein analyte tests on human biological fluid samples.

Main functions, identified by specific icons on the left of the screen (Fig. 7. 3)

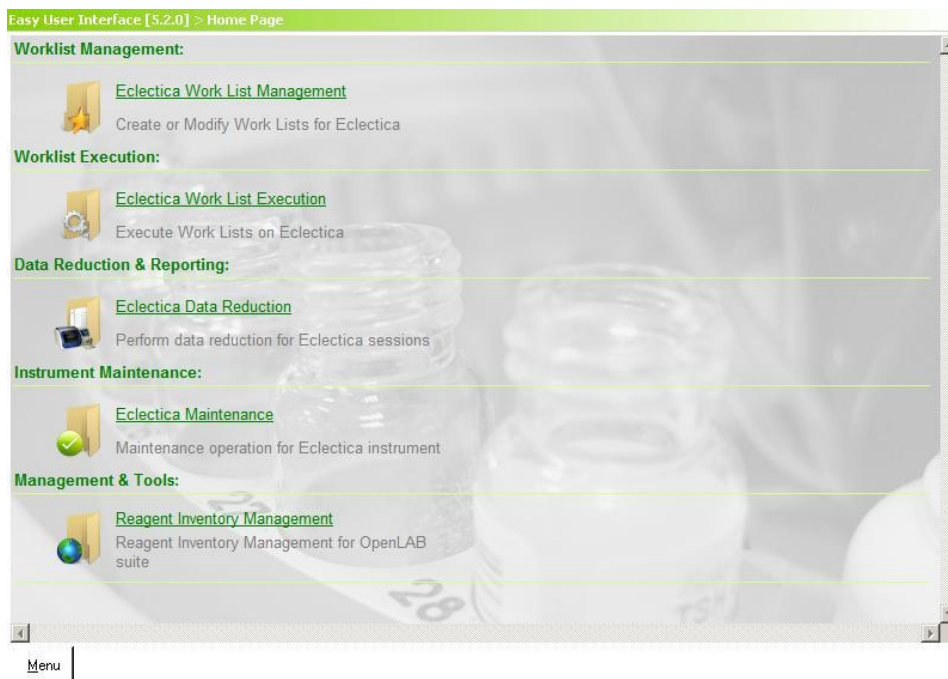
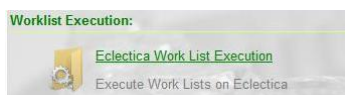


Fig. 7. 3

Icons on the left side of the screen:

**worklists Management (WLM)**

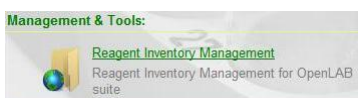
Used to create, edit and save worklists

**worklist Execution (WLE)**

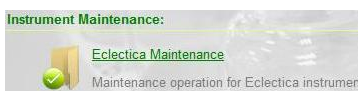
Used to execute worklists that have already been created and/or perform calibration/standardization operations.

**Data Reduction and Reporting:**

Used to display and print out the results of the worklists executed.

**Reagents management (RIM):**

Reagents Warehouse. Provides the facility to manage warehouses and contents, loading and unloading the materials required for the correct execution of each work session.

**Instrument Maintenance:**

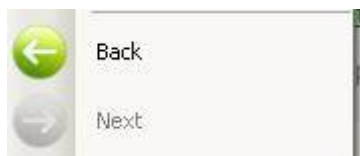
Used to carry out all maintenance activities (cleaning the instrument, replacing Common Reagents, changing Reaction Segments, emptying the Waste Tank, performing the autozero procedure) that may be required.

See Section 8, "Maintenance", for details.

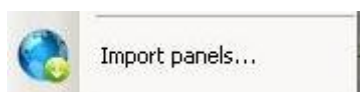
The additional functions, which are identified by specific icons on the side bar of the Main Menu (accessible by clicking on the "Menu" button, at the bottom left), are:

**Home Page:**

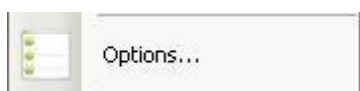
The **Home Page** button opens the main window of the Easy User Interface (fig. 7.1). It is used to go in the main page form another plugin.

**Back/Next:**

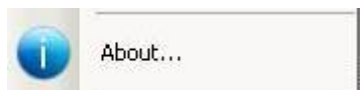
These buttons are used to navigate through the open plugins.

**Import Panels:**

The **Import Panels button** serves to import validated panels.

**Options:**

The Options button serves to set configurable software parameters (paths, reports, etc)

**About...**

The About... button is used to obtain information on the OpenLAB version

**Exit**

To close OpenLAB software.

Easy User Interface layout personalization

Click on the **Menu** and **Pages** buttons at the bottom left of each page to change the software layout.(Fig. 7. 4)

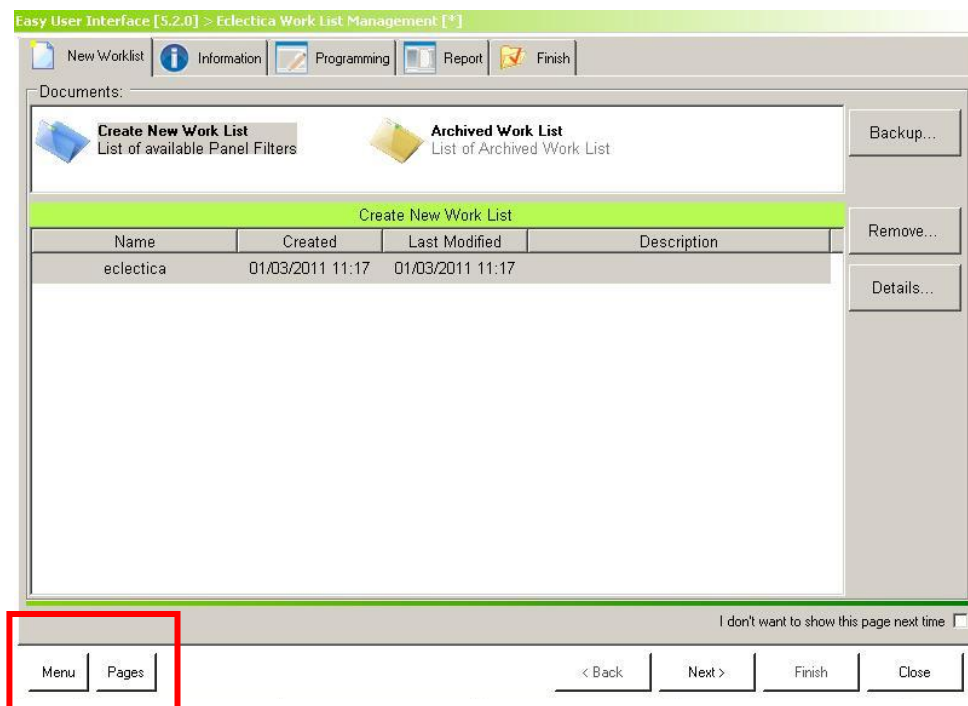


Fig. 7. 4

The following instructions describe how to:

- Hide the menu navigation bar.
- Hide the Title bar.
- Hide the status bar
- Move the menu lateral navigation bar.
- Hide the module tab pages

Display the Navigation bar:

Select the **Menu-> Options... button** and check the *Show Navigation Bar* option (Fig. 7. 5) to enable the side navigation bar display



Fig. 7. 5

Figure (Fig. 7. 6) shows the appearance of the main menu with the side navigation bar

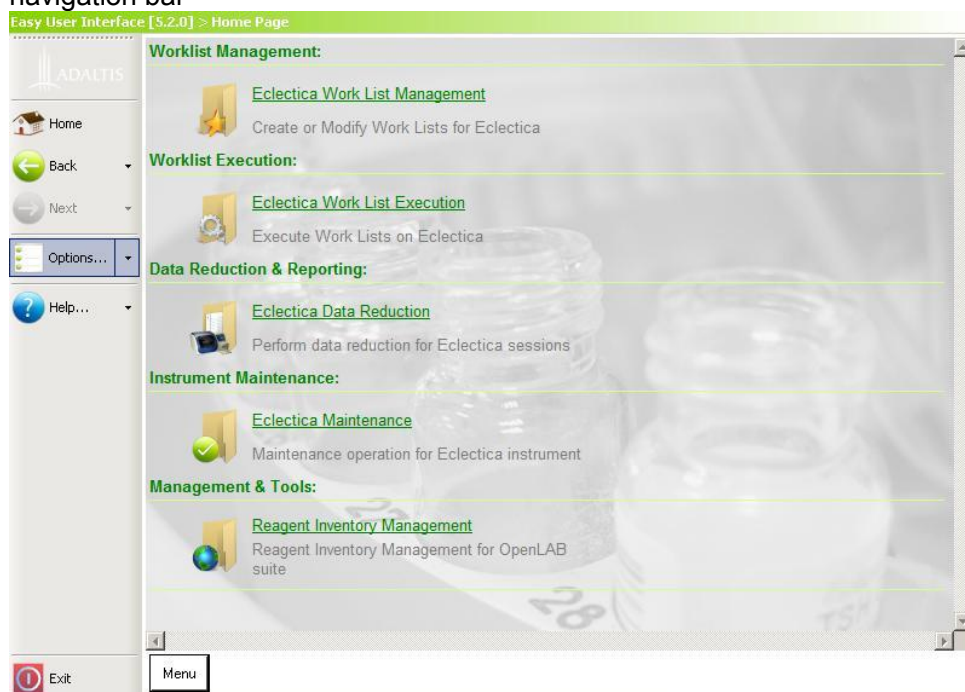


Fig. 7. 6

How to display the Title bar.

Select the **Menu-> Options... button** and check the *Show Title Bar* option (Fig. 7. 7) to hide the upper title bar.



Fig. 7. 7

The following screenshot shows the main menu with the title bar



Fig. 7. 8

How to display the Status Bar

Select the **Menu-> Options... button** and uncheck the *Show Status Bar* option (Fig. 7. 9) to hide the status bar.

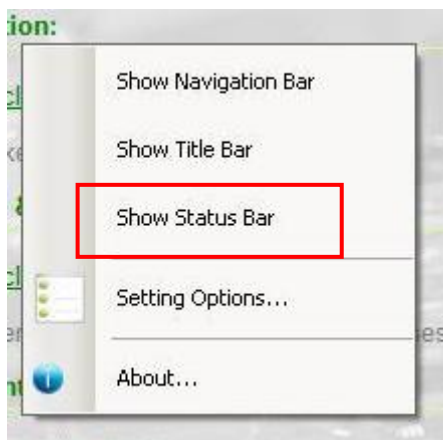


Fig. 7. 9

The screenshot (Fig. 7. 10) shows the appearance of the main menu with the status bar

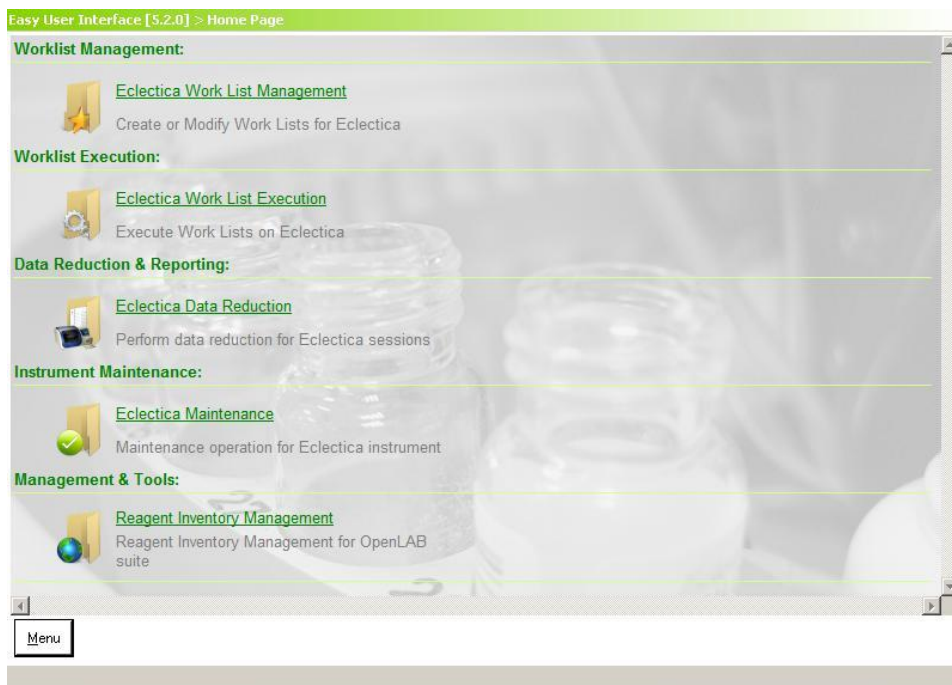


Fig. 7. 10

Repositioning the side menu navigation bar.

Select the side menu navigation bar in the dotted area shown by the red box in the following screenshot (Fig. 7. 11) and move the bar to the required position

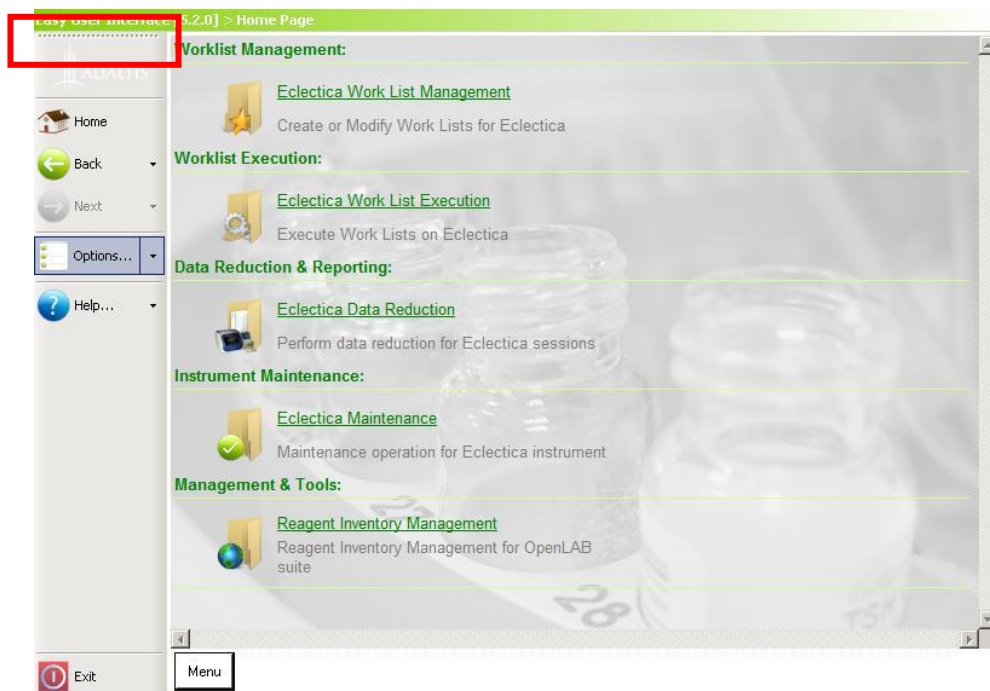


Fig. 7. 11

Several bar position examples are shown below:

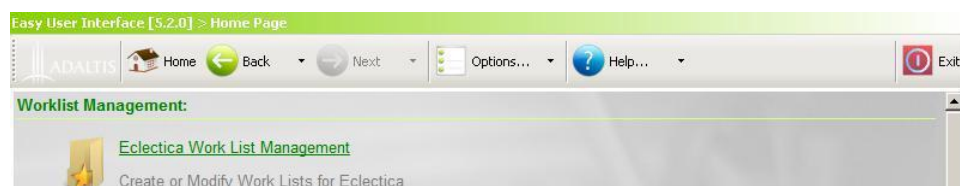
Bar at the top

Fig. 7. 12

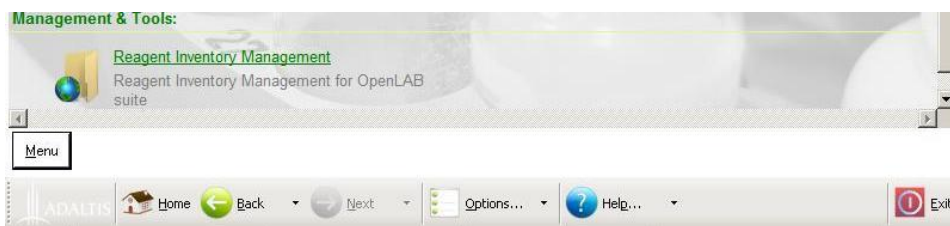
Bar at the bottom

Fig. 7. 13

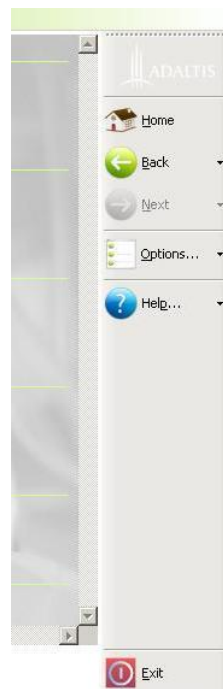
Bar on the right

Fig. 7. 14

How to hide the modules tab page

To disable module pages display (tab page Fig. 7.15)

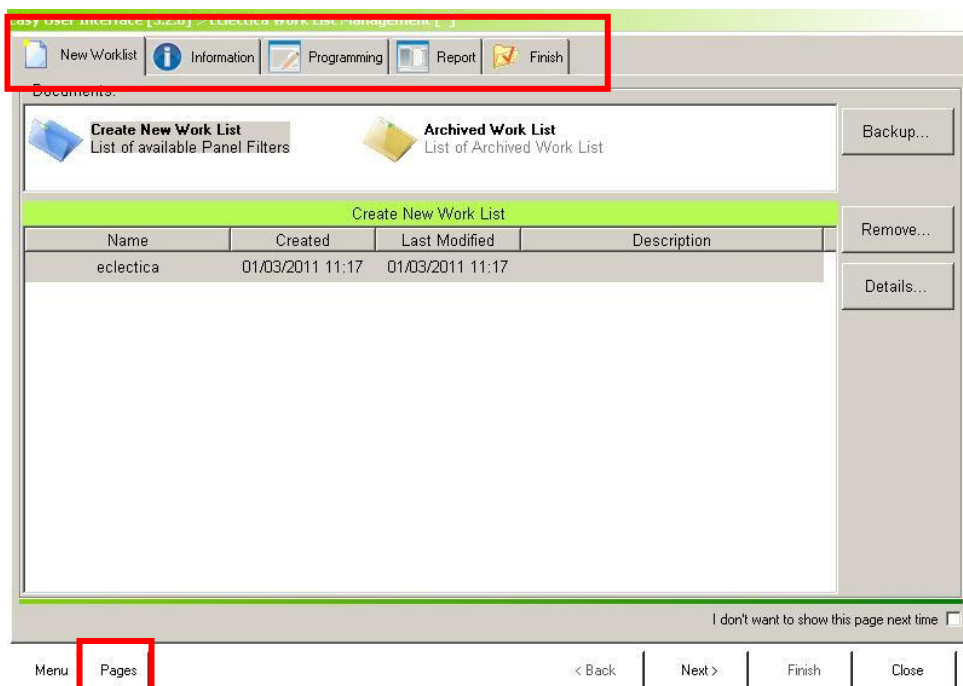


Fig. 7.15 - WLM module -

Select the **Pages** (Fig. 7.15) button and uncheck the *Show Tabs option* (Fig. 7. 16)

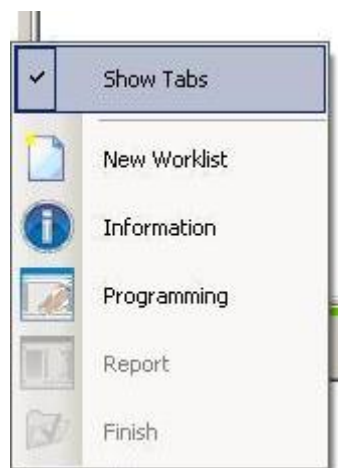


Fig. 7. 16

The selected module is displayed without the *tab* page (Fig. 7.17).

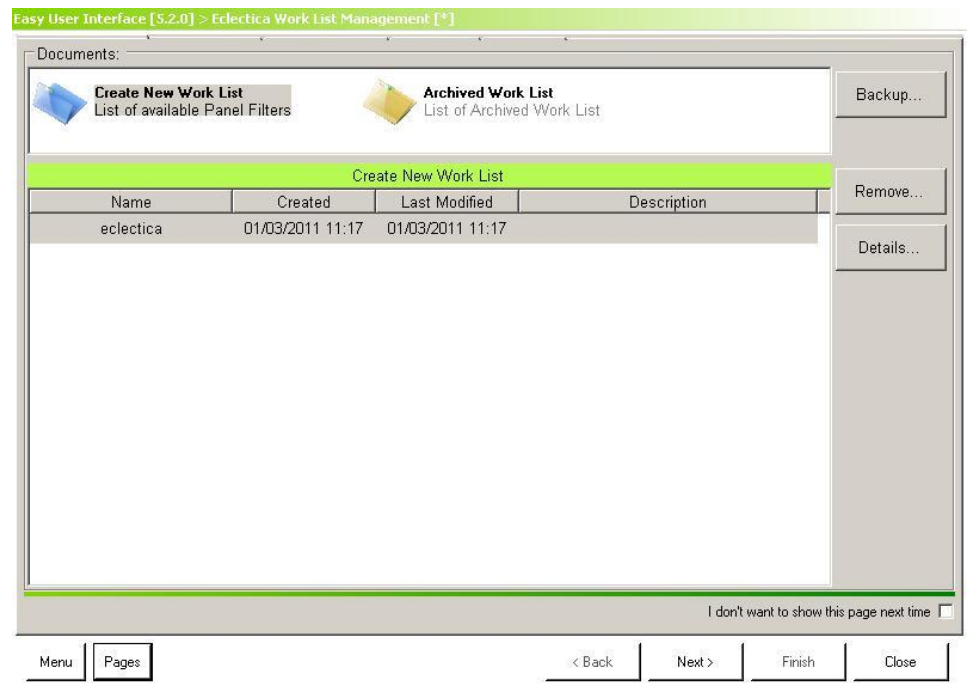


Fig. 7. 17

To select a page of the wizard, select the **Pages** button and choose the required page (Fig. 7. 18)

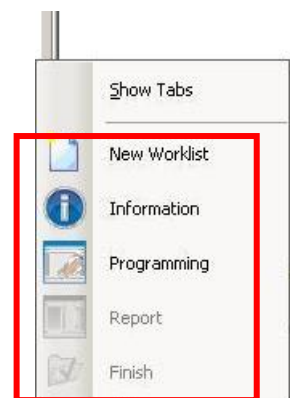


Fig. 7. 18

Loading Consumables: Reagents Inventory Management (RIM)

The ECLECTICA™ OpenLAB software provides the facility to manage reagents warehouses and their contents, load and unload the necessary material for correct execution of each work session

- Automatic uploading of data regarding the consumables for running Immunoassay, Clinical Chemistry tests.
- Consulting the status of the consumables present in the warehouse

From the Main Menu page, select the "Reagent Inventory Management" icon (Fig. 7. 19)

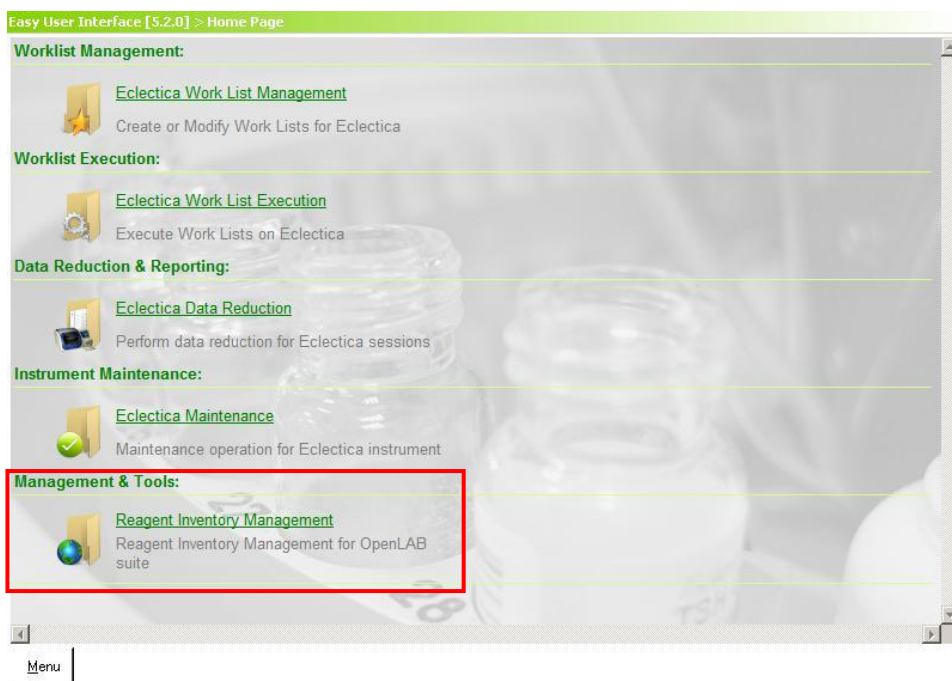


Fig. 7. 19

Reports

The **report page** (Fig 7.20) shows all the consumables present in the warehouse expressed in terms of kits, with an indication of the relative lot and expiry date. Additional information supplied concerns:

- the number of tests available for each kit.
- the values of ODs and mastercurve concentrations (for IA) and C1 and C2 controls
- the values of calibration kit concentrations
- the concentration values of each analyte for multiparametric calibrators.

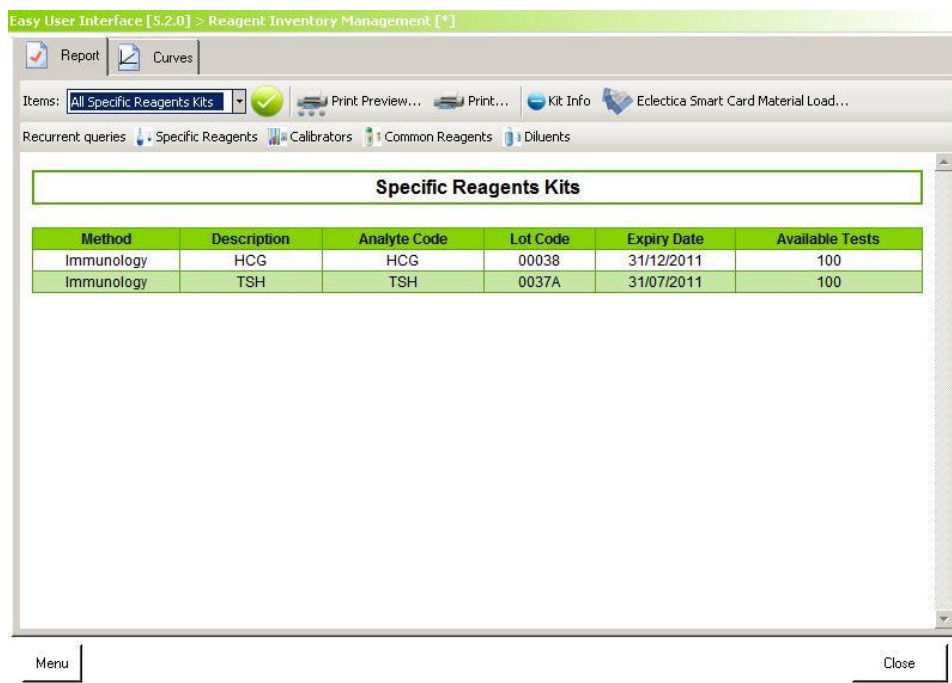


Fig 7.20

You can make various warehouse searches by selecting (Fig. 7. 21) the query required in the **Query** drop-down box, or by clicking on the buttons relative to the most frequently used queries:



Fig. 7. 21

1. **AllAvailableTestForPackage:** Performs a search for consumables per package type, from among the available (uploaded) materials
2. **Select Calibration Kit:** Performs a search for calibration kits (excluding multi-calibrators) per type of test
3. **Select Common Reagents Kit:** performs a search for IA common reagents kit
4. **Select Diluents Kit:** Performs a search for diluents for Immunoassay tests (IA)
5. **Multicalibrators:** Performs a search for multiparametric calibration kits (for CC)
6. **Specific Reagent Kit:** Performs a search for a specific reagent kit among those uploaded
7. **All Calibrators Kit:** Shows all calibration kits uploaded. The shortcut button is *Calibrators*
8. **All Common Reagents Kit:** Shows all common reagents kits for Immunoassay tests (IA) uploaded. The shortcut button is *Common Reagents*
9. **All Diluents Kits:** Shows all diluents kits for Immunoassay tests uploaded. The shortcut button is *Diluents*
10. **All Specific Reagents Kits:** Shows specific reagent kits uploaded. The shortcut button is *Specific Reagents*

SEARCHING FOR A PACKAGE:

To search for specific package in the warehouse, in the drop-down **Query** box (Fig. 7. 21) select the query *AllAvailableTestForPackage*

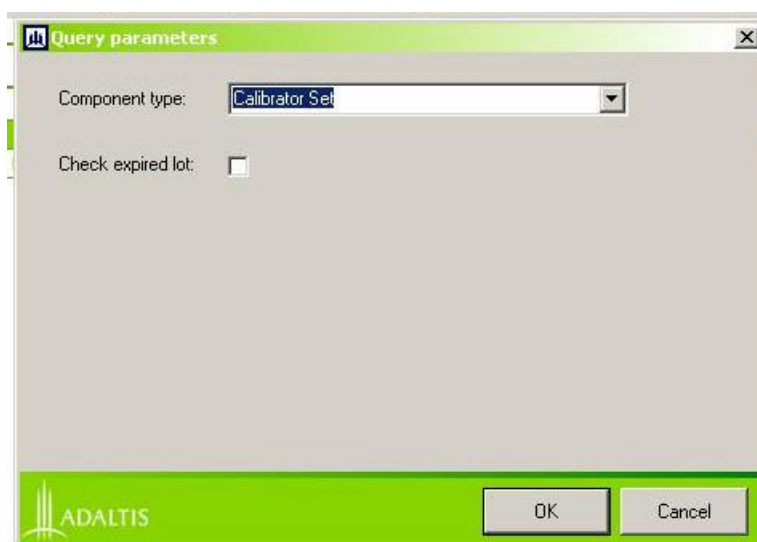


Fig. 7. 22

When the dialogue box (Fig. 7. 22) *Component type* opens, select one of the specified packages, e.g. *Calibrator Set*.

Press **OK**

A report is displayed (Fig. 7. 23) with all the consumables found in the Eclectica warehouse for the selected package.

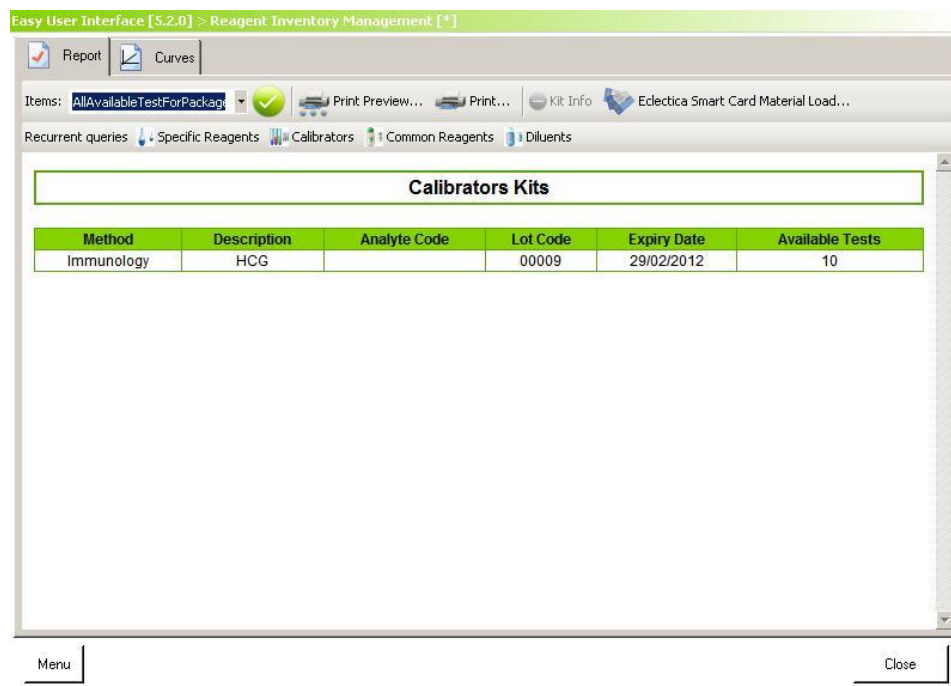


Fig. 7. 23

Select *Check expired lot* (Fig. 7. 23) to check also the packages of the selected component for which the lot has expired.

KIT INFO:

Through the *Kit Info* button (Fig. 7.24) it's possible (Fig. 7.25):

1. to display the available lots for the relevant analyte (*Analyte Code + Lot*)
2. to display the number of available tests for each lot (*Available tests*)
3. to delete the selected lot (*Delete Lot*)
4. to decrease the number of available tests for the selected lot (*Update tests*)



Fig. 7. 24

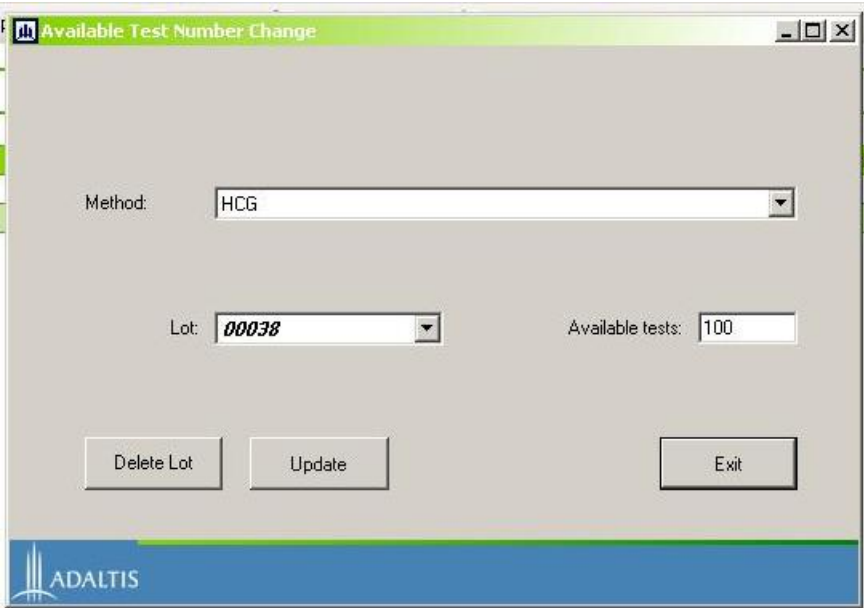


Fig. 7. 25

Curves

The **curves** page (Fig. 7.26) displays the status of the lots relative to the reagents uploaded to the warehouse

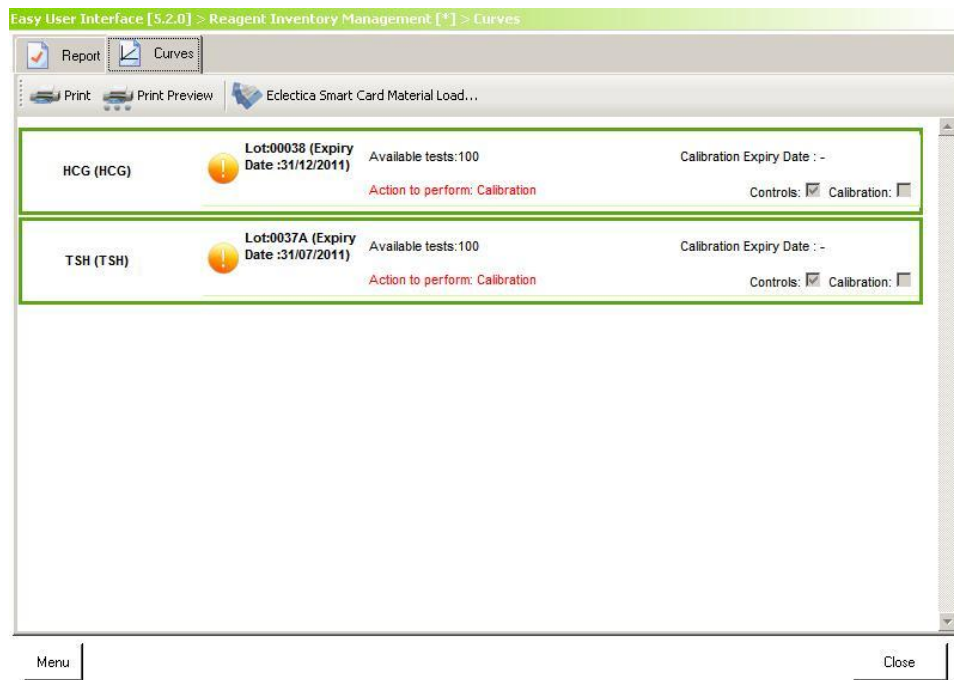


Fig. 7. 26



The symbol indicates that the kit is valid and can be used, although a calibration check is required. Further possibilities include:



Indicates that kit and calibration are both valid

The Curves page is automatically updated by loading the Smart Card relative to the specific reagent

Uploading Data from Smart Card

Press "**Load Material....**" (Fig. 7.27) on the bar at the top right

A message is displayed prompting the user to insert the Smart Card (Fig. 7.27). For more details, please read the following pages.

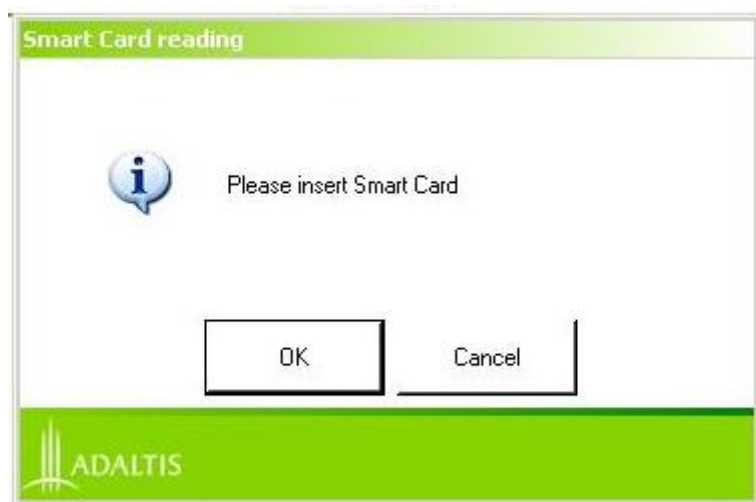


Fig. 7. 27

Package 01: Specific Reagents Kit upload

The methods used to upload data and install vials of Specific Reagents and Controls are described below.

Data upload

Open the package of Specific Reagents and remove the Smart Card (Fig. 7.28)



Fig. 7. 28

Press "**Eclectica Smart Card Load Material....**" on the bar at the top right (Fig. 7.27)

A window will appear displaying the message: ***Insert Smart Card (Insert the Smart Card in the reader)***

Insert the Smart Card with the writing facing upwards and the chip facing the instrument.

Wait for the red light on the reader to go out.

When the data have been uploaded, the message ***Remove Smart Card will be displayed.***

After the data have been uploaded from the Smart Card, the following information will appear on the ***Smart Card Viewer page*** (Fig. 7.29) for each method:

Master Curve		
	Concentration	OD
Cal. A	0	0.138
Cal. B	0.360	0.289
Cal. C	1.060	0.564
Cal. D	3.710	1.580
Cal. E	11.500	4.032
Cal. F	46.200	9.334
Cal. G	0	0

Controls		
	Concentration	OD
Ctrl. 1	0.530	0.353
Ctrl. 2	7.200	2.775

Fig. 7.29

- Method Code,
- Lot Code,
- Expiry date,
- Tests Available,
- Smart Card serial number and barcode,
- Master Curve: Optical concentration and density values of the calibration curve,
- Controls: Optical concentration and density values.

Press **OK** (Fig. 7.29), and remove the Smart Card. Once the Smart Card has been used it cannot be used again.

Loading vials

The vials of Specific Reagents must be inserted in the internal ring of the Reagents Plate in positions 1-20.

The Controls (Control 1 and Control 2) must be inserted in the external ring of the Reagents Plate in positions 1-28 (see Fig. 7.30).

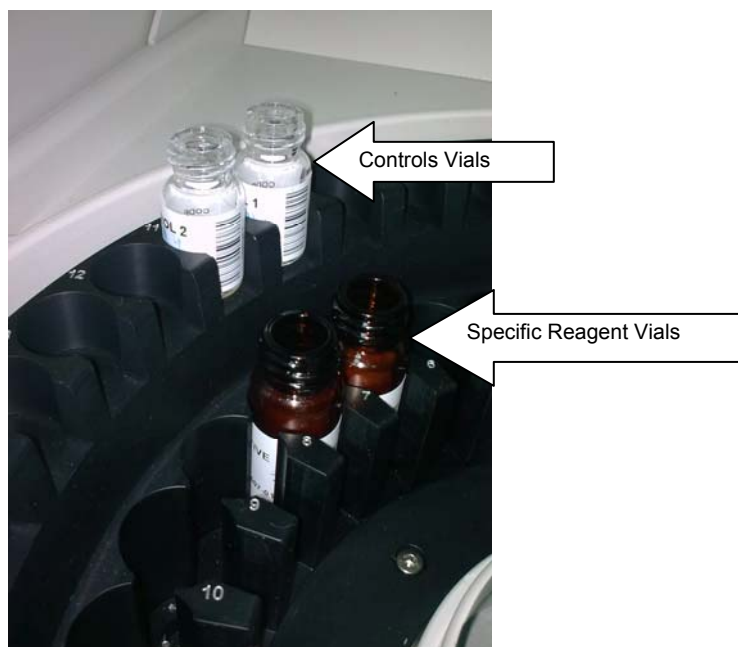


Fig. 7.30

NOTE: Each Specific Reagent and Control vial has a label with a barcode that must be oriented so that the barcode reader can scan it.

The loading position is unimportant since the instrument will automatically identify the positions by way of the barcode reader.



WARNING: Before using the analyzer, make sure that all the caps on the vials installed on the instrument have been removed, thereby preventing collision with the Sampling Needles.

Package 02: Loading Common Reagents Kit (Substrate, Stop Solution, Separation Agent)

The methods used to upload data and install vials of Common Reagents are described below.

Data upload

Open the package of Common Reagents and remove the Smart Card.



Smart Card

Press "**Eclectica Smart Card Load Material....**" on the bar at the top right (Fig. 7.27)

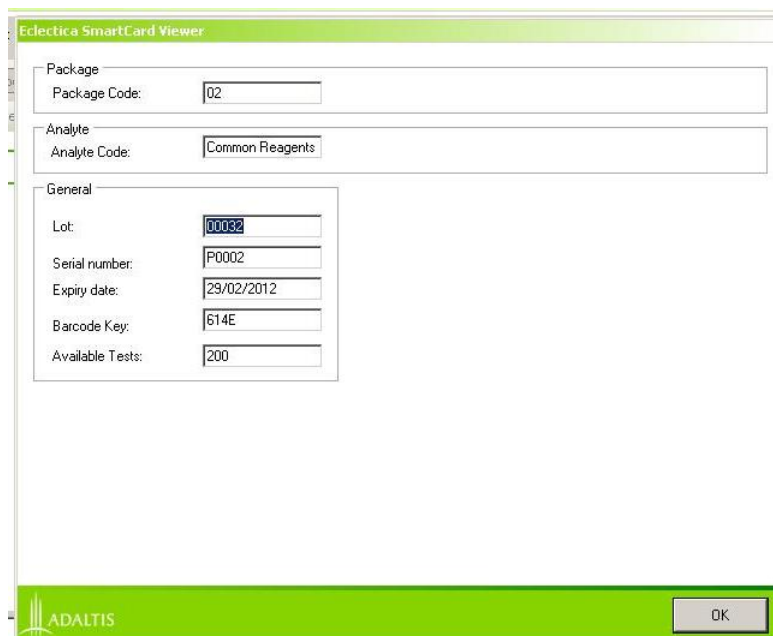
A window will appear displaying the message **Insert Smart Card (Insert the Smart Card in the reader)**

Insert the Smart Card with the writing facing upwards and the chip facing the instrument.

Wait for the red light on the reader to go out.

When the data have been loaded, the message **Remove Smart Card** will be displayed.

After the data have been loaded using the Smart Card, the following information relative to the Common Reagents Kit loaded will appear on the **Smart Card Viewer page** (Fig. 7.31):



Edlectica SmartCard Viewer	
Package	
Package Code:	02
Analyte	
Analyte Code:	Common Reagents
General	
Lot:	00032
Serial number:	P0002
Expiry date:	29/02/2012
Barcode Key:	614E
Available Tests:	200
ADALTIS	
OK	

Fig. 7.31

- Lot Code
- Expiry date
- Tests Available
- Smart Card serial number and barcode.

Press **OK** (Fig. 7.31) and remove the Smart Card. Once the Smart Card has been used it cannot be used again.

Loading vials/containers

The vials of Common Reagents (substrate and stop solution) must be installed on the analyzer as described in: *""Connecting the Waste tank/Accessory vials""* in Section 3: ***"Installation"***, and the container of Separation Agent must be installed at the centre of the Samples Carousel.

Remove the container of Separation Agent from the package of Common Reagents, remove the red cap and place the container in the specific well in the Samples Carousel (see Fig. 7.32).

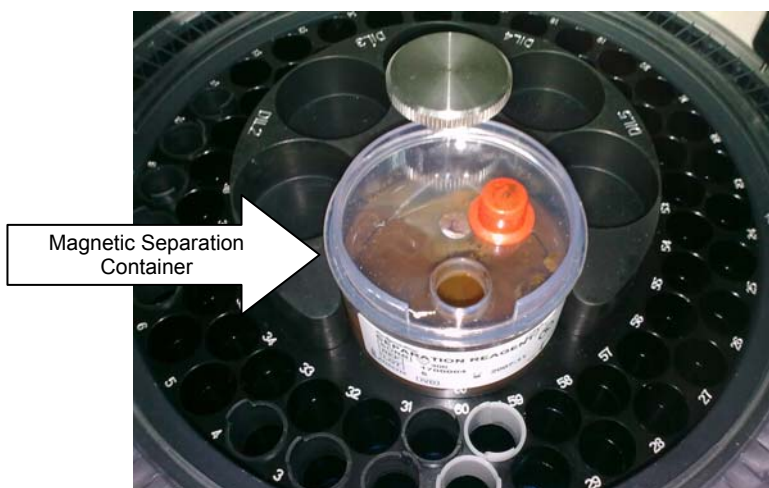


Fig. 7.32



WARNING: In order to avoid possible contamination of the reagents, do not place the vial caps on the work surface when they are removed. The caps can be reused.



WARNING: Before using the analyzer, make sure that the red cap on the Separating Agent container has been removed thereby avoiding collision with the Sampling Needles.

Once the vials of Substrate and Stop Solution and the Separation Agent container have been installed, carry out the procedure for replacement of Common Reagents described in Section 8 **"Replacing Common Reagents"**.

Loading the Wash Solution

The bottles of Systemic Wash Solution and Immunoassay Washing Buffer must be installed on the instrument as described in: *"Connecting the Waste Tank/Accessory bottles"* in Section 3: **"Installation"**

Package 03: Diluents kit

The methods used to upload data and install Diluent bottles are described below.

Data upload

Open the package of Diluents and remove the Smart Card.



Smart Card

Press "**Eclectica Smart Card Load Material....**" on the bar at the top right (Fig. 7.27)

A window will appear displaying the message: **Insert Smart Card (Insert the Smart Card in the reader)**

Insert the Smart Card with the writing facing upwards and the chip facing the instrument.

Wait for the red light on the reader to go out.

When the data have been loaded, the message **Remove Smart Card** will be displayed.

After the data have been loaded using the Smart Card, the following information relative to the Diluent Kit will appear on the **Smart Card Viewer page** (Fig. 7.33):

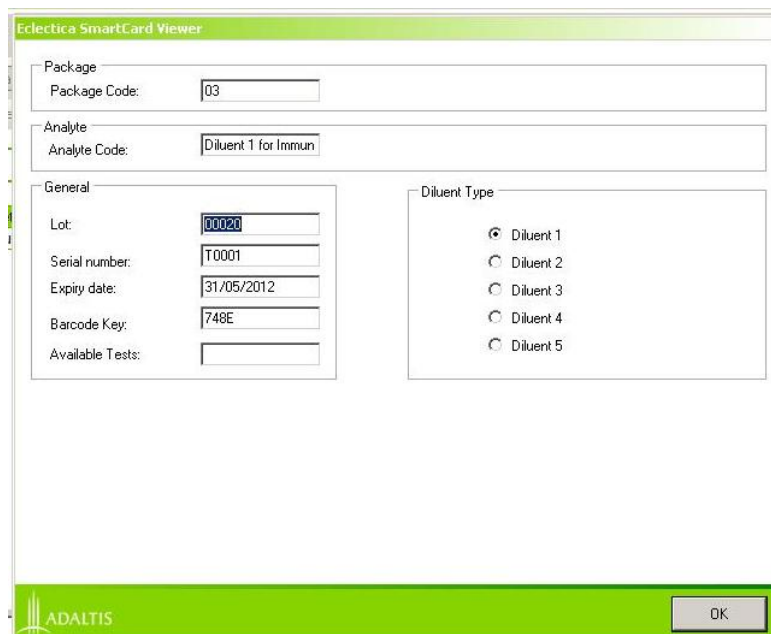


Fig. 7.33

- Lot Code.
- Expiry date
- Max Volume (maximum volume contained in a pack: 3 x 20 ml bottles = 60 ml).
- Smart Card serial number and barcode.
- Type of Diluent: Diluent 1, Diluent 2, Diluent 3, Diluent 4, Diluent 5.

Press **OK** (Fig. 7.33) and remove the Smart Card. Once the Smart Card has been used it cannot be used again.

Loading bottles

The Diluent bottles must be inserted in the specific wells located at the centre of the Samples Carousel (see Fig. 7.34).

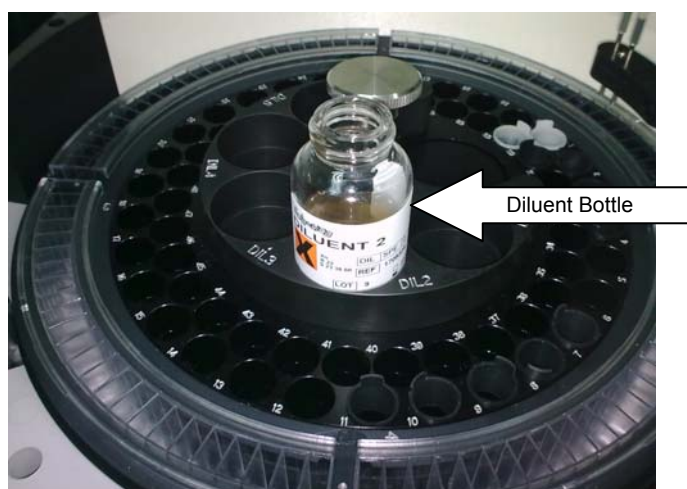


Fig. 7.34



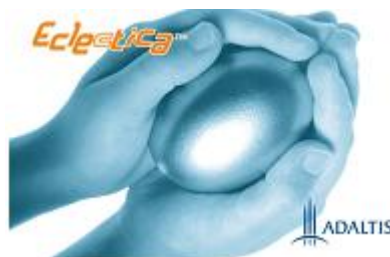
WARNING: Before using the instrument, make sure that all the caps on the vials and bottles installed on the analyzer have been removed, thereby preventing collision with the Sampling Needles.

Package 04: Calibration Kit

The methods used to upload data and install Calibrator vials are described below.

Data upload

Open the Calibration Kit package and remove the Smart Card.



Smart Card

Press "**Eclectica Smart Card Load Material....**" on the bar at the top right (Fig. 7.27)

A window will appear displaying the message **Insert Smart Card in reader.**

Insert the Smart Card with the writing facing upwards and the chip facing the instrument.

Wait for the red light on the reader to go out.

When the data have been loaded, the message **Remove Smart Card** will be displayed.

After the data have been loaded using the Smart Card, the following information will appear on the **Smart Card Viewer page** (Fig. 7.35), relative to the Calibration Kit:

Eclectica SmartCard Viewer	
Package	
Package Code:	04
Analyte	
Analyte Code:	HCG
General	
Lot:	00003
Serial number:	P0003
Expiry date:	29/02/2012
Barcode Key:	543E
Available Tests:	10
Calibrators	
Concentration	
Cal. A:	0
Cal. B:	4.210
Cal. C:	21.900
Cal. D:	99.800
Cal. E:	243.100
Cal. F:	485.400
Cal. G:	0

Fig. 7.35

- Method Code.
- Lot Code.
- Expiry date.
- Tests Available.
- Smart Card serial number and barcode.
- Concentration values of the calibration curve

Press **OK** (Fig. 7.35), and remove the Smart Card. Once the Smart Card has been used it cannot be used again.

Loading Calibrator vials for Immunoassay tests

The Calibrator vials must be inserted in the external ring of the Reagents carousel in positions 1-28 (see Fig. 7.36).

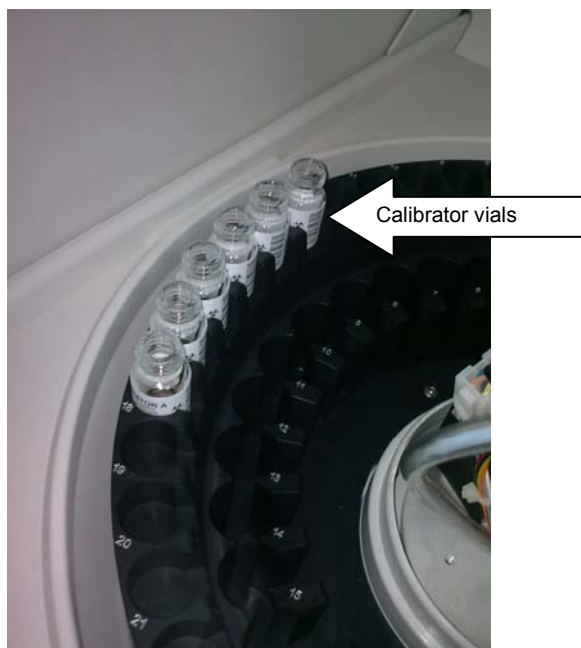


Fig. 7.36

NOTE: Each calibrator vial has a label with a barcode that must be oriented so the barcode reader can scan it.

The loading position is unimportant since the instrument will automatically identify the positions by way of the barcode reader.



WARNING: Before using the analyzer, make sure that all the caps on the vials installed on the instrument have been removed, thereby preventing collision with the Sampling Needles.

Package 06: Specific Reagents for Clinical Chemistry tests**Data upload**

Open the package of Specific Reagents and remove the Smart Card.

Press "***Eclectica Smart Card Load Material....***" on the bar at the top right (Fig. 7.27).

A window will appear displaying the message: ***Insert Smart Card (Insert the Smart Card in the reader)***

Insert the Smart Card with the writing facing upwards and the chip facing the instrument.

Wait for the red light on the reader to go out.

When the data have been loaded, the message ***Remove Smart Card will be displayed.***

After the data have been loaded using the Smart Card, the following information will appear on the ***Smart Card Viewer page (Fig. 7.37)*** for each method:

The screenshot shows the 'Eclectica SmartCard Viewer' window. It contains the following fields and values:

- Package Code: 06
- Analyte Code: URICA
- General section:
 - Lot: 08026
 - Serial number: P0005
 - Expiry date: 31/08/2011
 - Barcode Key: 978C
 - Available Tests: 120
- Reagent Codes section:
 - Rea. 1: 65
 - Rea. 2: 66

The ADALIS logo is visible in the bottom left corner, and an OK button is in the bottom right corner.

Fig. 7.37

- Method Code
- Lot Code
- Expiry date

- Tests Available
- Smart Card serial number and barcode.

Press **OK (Fig. 7.37)**, and remove the Smart Card Once the Smart Card has been used it cannot be used again.

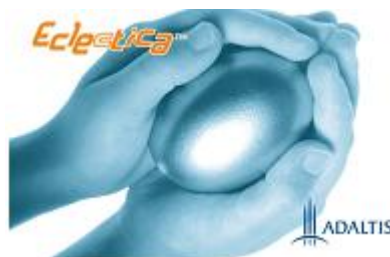
Load then reagent vials as described in paragraph “**Package 01: Specific Reagents Kit upload**”. (NOTE: no C1/C2 calibrators for CC tests!).

Package 07: Parametric Multicalibrator

The following section describes the methods used to load data and vials of Parametric Multicalibrator.

Data upload

Open the *Parametric Multicalibrator* package and remove the Smart Card.



Smart Card

Press "**Eclectica Smart Card Load Material....**" on the bar at the top right (Fig. 7.27)

A window will appear displaying the message **Insert Smart Card (Insert the Smart Card into the reader)**

.

Insert the Smart Card with the writing facing upwards and the chip facing the instrument.

Wait for the red light on the reader to go out.

When the data have been loaded, the message **Remove Smart Card will be displayed.**

After the data have been loaded using the Smart Card, the following information relative to the Multicalibrator will appear on the **Smart Card Viewer page** (Fig. 7.38):

General		Calibrators			
		Meth. Code	Conc.	Meth. Code	Conc.
Lot:	80018	ALP	445	GGT	93
Serial number:	T0004	ALT	91.300	GLUC	186
Expiry date:	30/06/2011	AMY	183	IRON	183
Barcode Key:	967A	AST	95.500	LDH_P	502
Available Tests:	300	DBIL	1.940	PHOS	5.080
		TBIL	5.140	TPROT	5.050
		CA	9.860	TRIG	140
		CHOL	150	UREA	99
		CK	313	URICA	5.410
		CREA	3.660		
		CL	101		

Fig. 7.38

- Method Code
- Lot Code
- Expiry date
- Tests Available
- Smart Card serial number and barcode
- Concentration values for each analyte in the calibrator

Press **OK** (Fig. 7.38), and remove the Smart Card. Once the Smart Card has been used it cannot be used again.

Preparing and loading the Parametric Multicalibrator

Open the *Parametric Multicalibrator* package and remove one of the multicalibrator vials. Reconstitute the material as per the Instructions for Use

Pour the contents of the vial into a sample tube and place it in the Samples Carousel (Fig. 7.39)

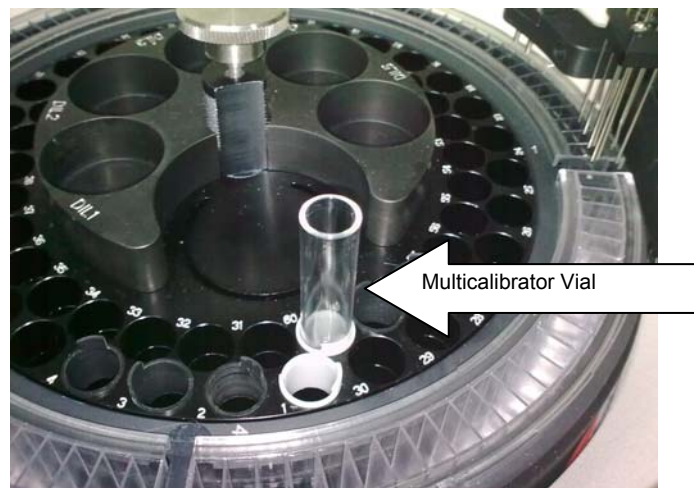


Fig. 7.39



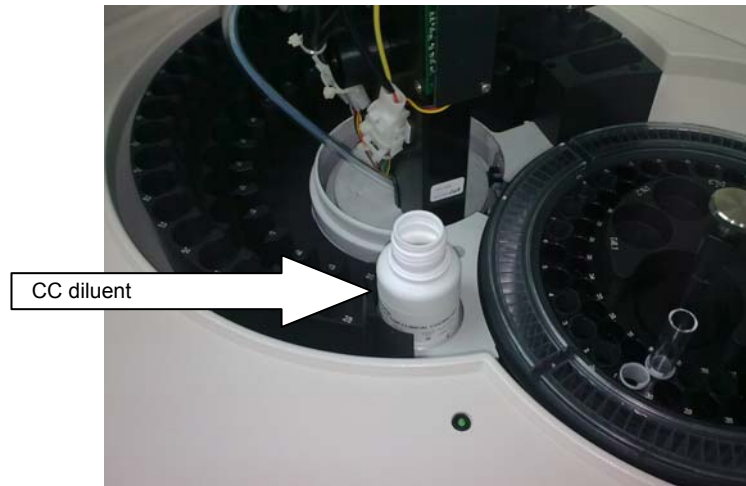
WARNING: The position of the Parametric Multicalibrator sample tube is established by the software during Resources management.



WARNING: To calibrate a Clinical Chemistry protocol, see Curves Section: Calibration curve management. On termination of the calibration procedure, remove the multicalibrator tube from the samples carousel.

Loading Diluents

The vial of Diluent for Clinical Chemistry tests must be loaded into its well in the outer ring of the Reagents carousel



Loading Common Reagents (Wash Solutions)

The Systemic Wash Solution and Immunoassay Washing Buffer bottles (Fig. 7.40) must be installed on the instrument as described in: *"Connecting the Waste Tank/Accessory Bottles"* in Section 3: *"Installation"*

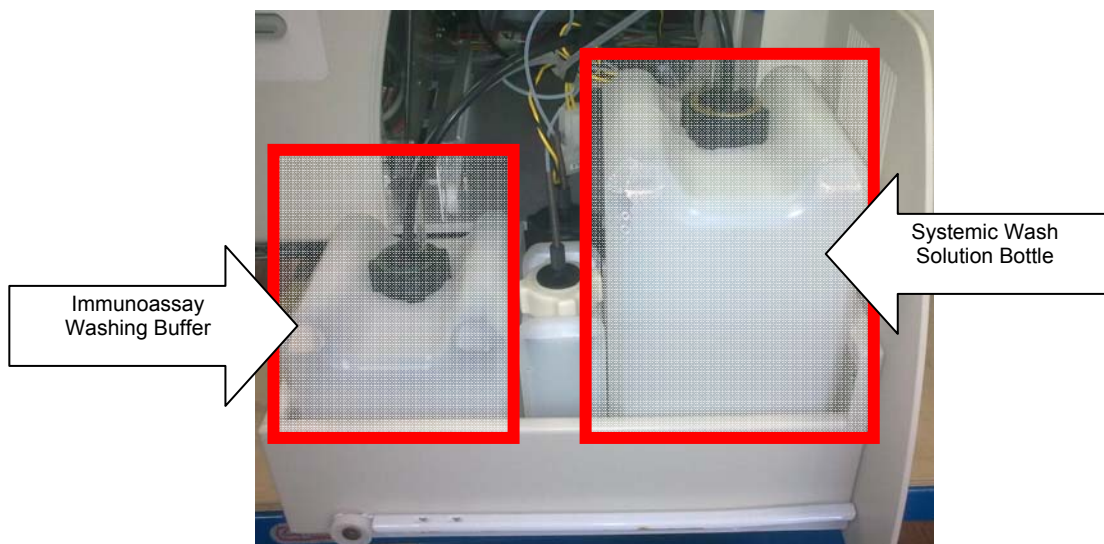


Fig. 7.40

Preparing/Storing/Using Consumables

Refer to the instructions for use for each kit.

Programming a Worklist

The ECLECTICA OpenLAB software provides the facility to create, edit, and save worklists to be run.

From the Main Menu page, select the *Eclectica Worklist Management* icon (Fig. 7.41)

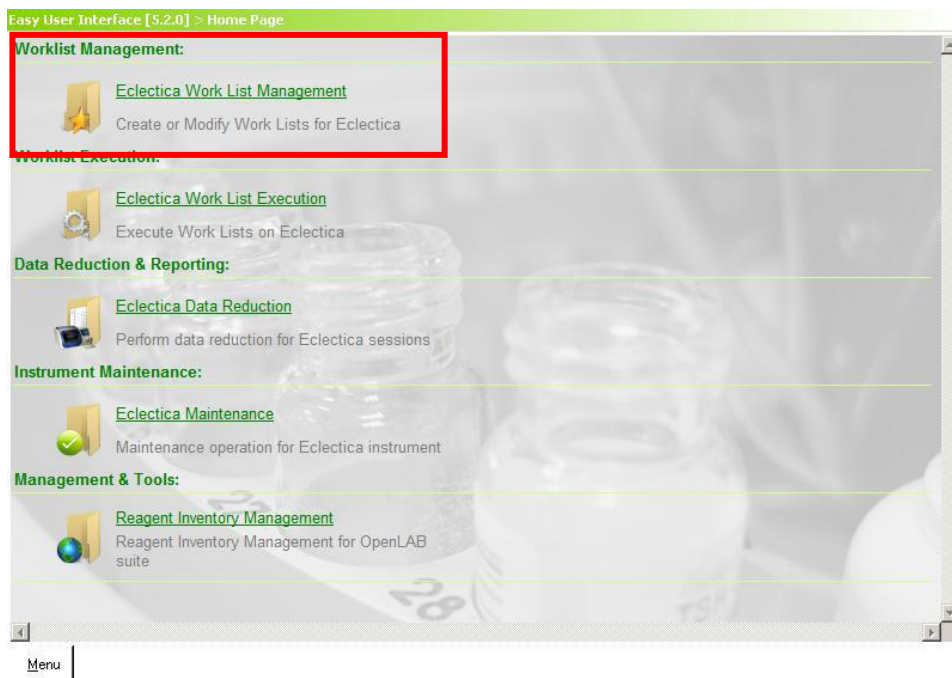


Fig. 7.41

New Worklist

The panels that can be executed on the instrument are shown in the centre of the page

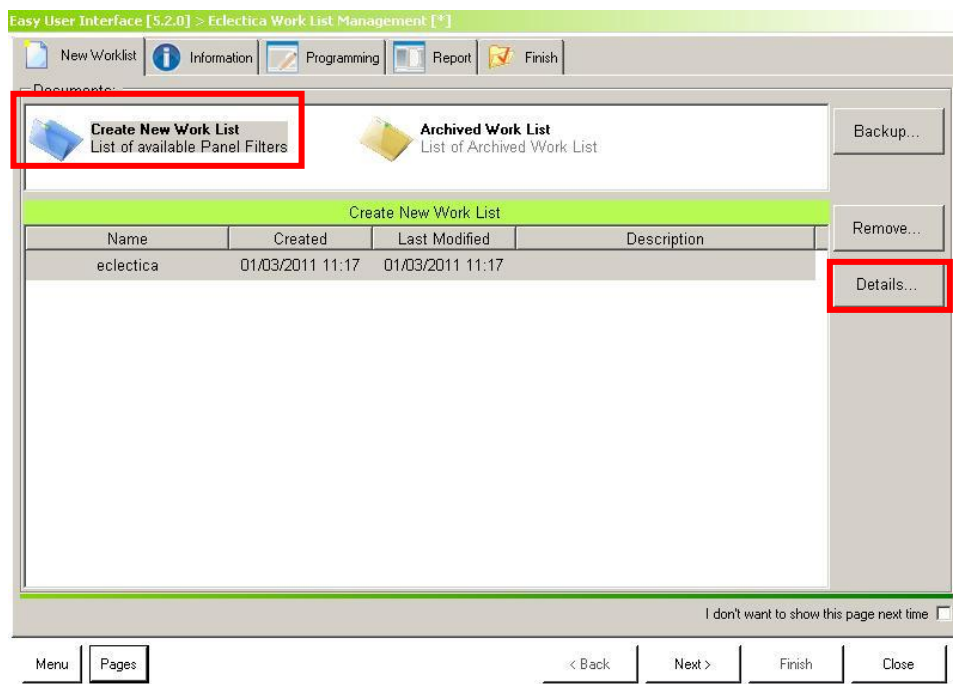


Fig. 7. 42

For details on the methods included in each panel select the panel and press **Details...** (Fig. 7. 43)

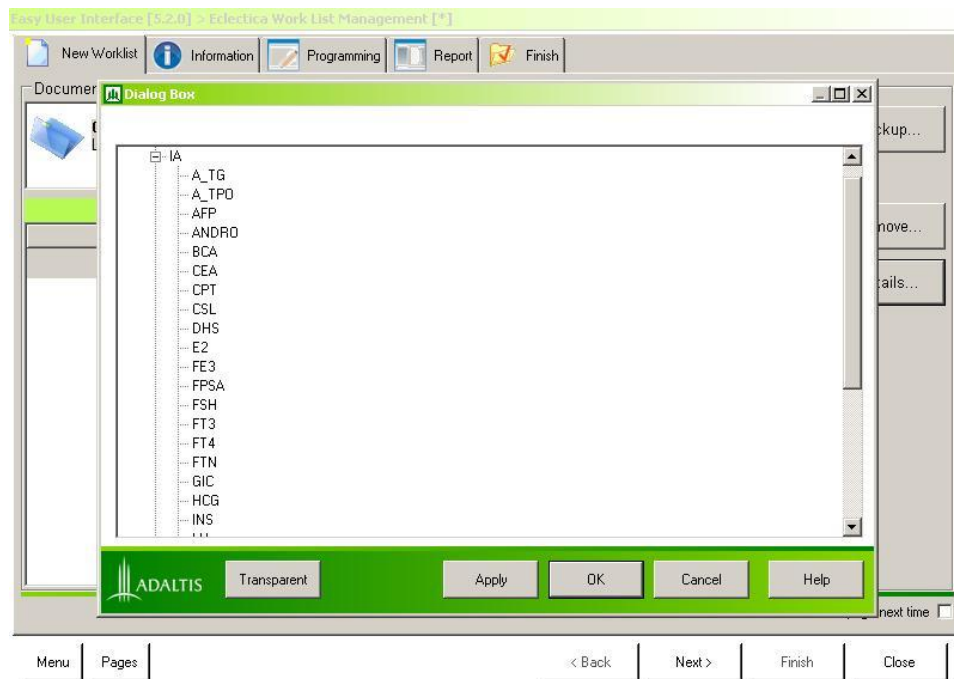


Fig. 7. 43

Click on **OK** or **Cancel** (Fig. 7. 43)

Select *Create a new worklist* (Fig. 7.45) and press *Next>* to go to the *Information* section.

Opening a saved Worklist

Select **Archived Worklist**

The list of the saved worklists is displayed

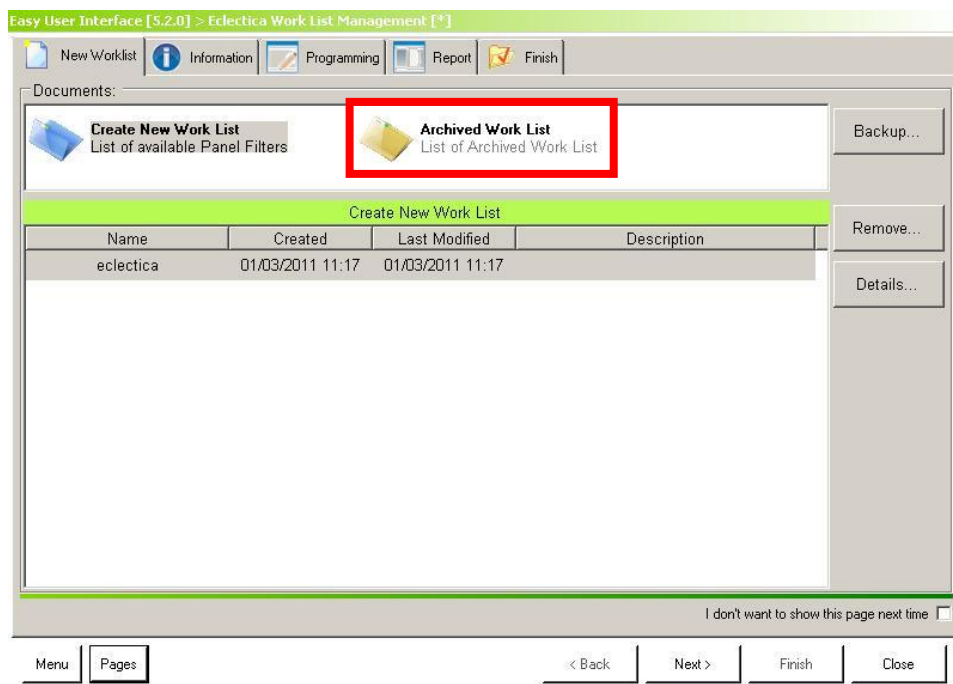


Fig. 7. 44

Select the list of interest and press **Next>** to go to the specific samples programming section.

Information

In **Information** section enter the name of the worklist and press **Next** to go to the section reserved for programming samples. This step is optional, because you can skip directly from the worklist selection/creation page to the samples programming page.

Easy User Interface [5.2.0] > Eclectica Work List Management [Eclectica#00091] > Information

New Worklist Information Programming Report Finish

User data:

Name: Eclectica

Run #: 00091 Company: ADALTIS S.r.l.

Author name: User Date: 01 March 2011

Description: Test.

I don't want to show this page next time ☐

Menu Pages < Back Next > Finish Close

Fig. 7. 45

In this page you can:

- Enter/edit the name of the worklist
- Edit the worklist author's name
- Enter comments and/or descriptions

Samples Programming

The **Programming** section provides the facility to perform the following operations:

- Entering samples
- Programming the tests to be performed on samples
- Entering patient information
- Quality Control programming
- Automatic samples identification
- Managing lists from LIS: this function allows to recover previously executed programming as well

NOTE: It's possible to access the *Programming* tab skipping all the previous steps (*New Worklist* -> *Information*). The software will create an empty worklist anyway.

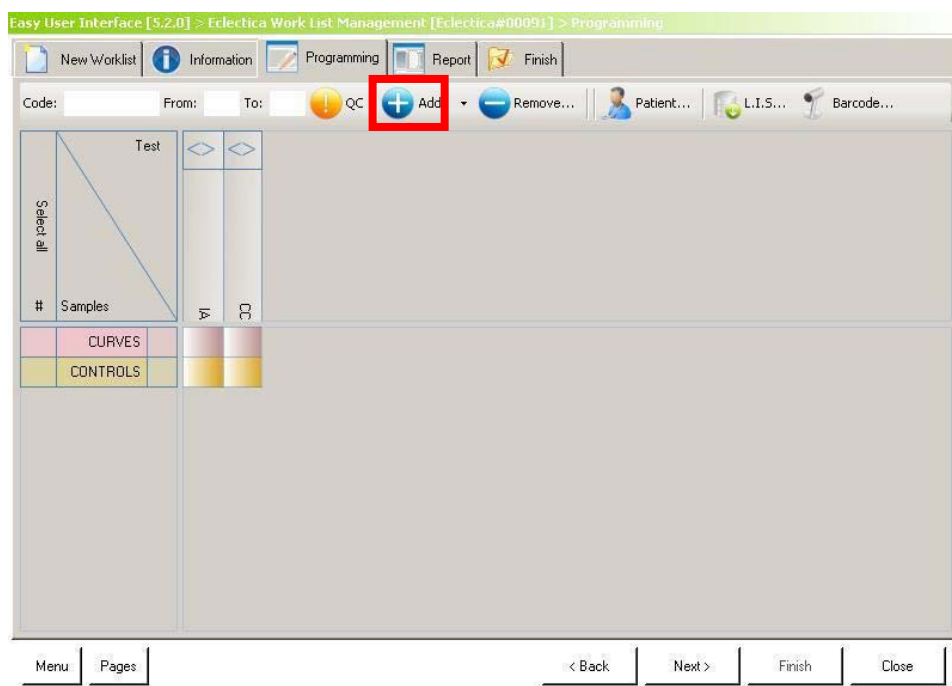


Fig. 7. 46

Samples Input:

Enter the name of the sample in the *Code* field and press **Add** (Fig. 7.47). If you want to identify the samples with the same name and a sequential number, enter the first number in the "From:" field and the last number in the "to:" field press **Add**.

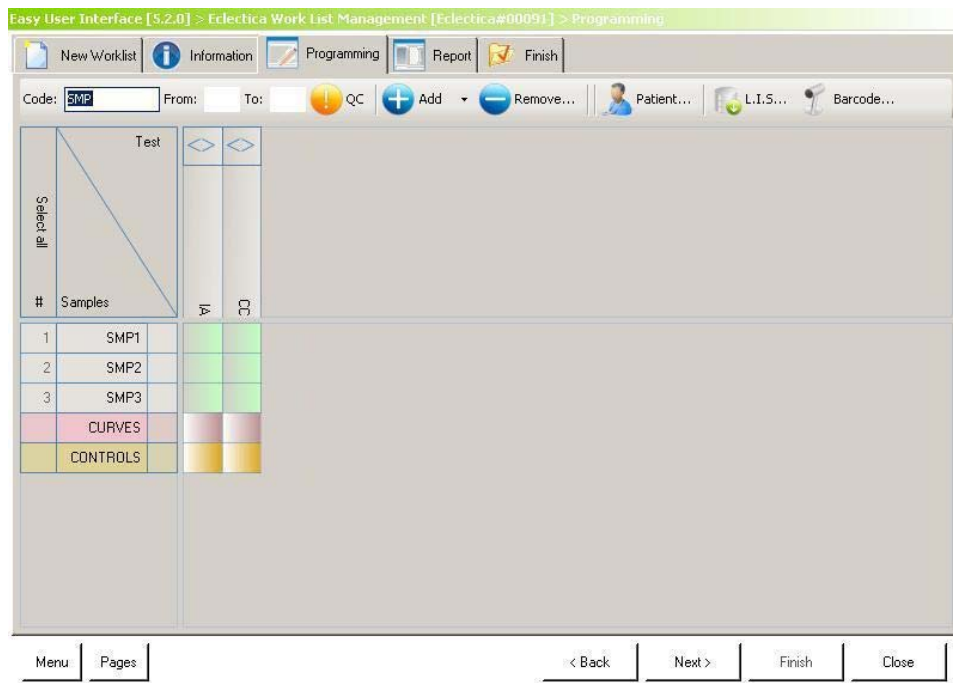


Fig. 7. 47

The columns contain, respectively, Immunoassay (IA) and Clinical Chemistry (CC) tests that can be executed on the analyzer (Fig.7.48).

To display the available tests click on the following symbol at the top of the page



Fig. 7. 48

The screenshot shows a grid titled 'IA' (Immunoassay) with columns for various tests and rows for sample types. The tests listed in the columns are: CC, FT3, FSH, FPSA, FE3, E2, DHS, CSL, CPT, CEA, BCA, ANDRO, AFP, A_TP0, and A_TG. The rows are color-coded: green for the first row, pink for the next two rows, and yellow for the last row. A red dot is visible in the cell corresponding to the 'TSH' test in the first row.

Fig. 7. 49 - Immunoassay Tests

Programming the Tests to be performed on samples:

- Select the row corresponding to the required sample
- Select the cell corresponding to the column with the name of the Test to be programmed.
- A red dot is displayed in correspondence with the test programmed on the selected sample (Fig. 7. 50).

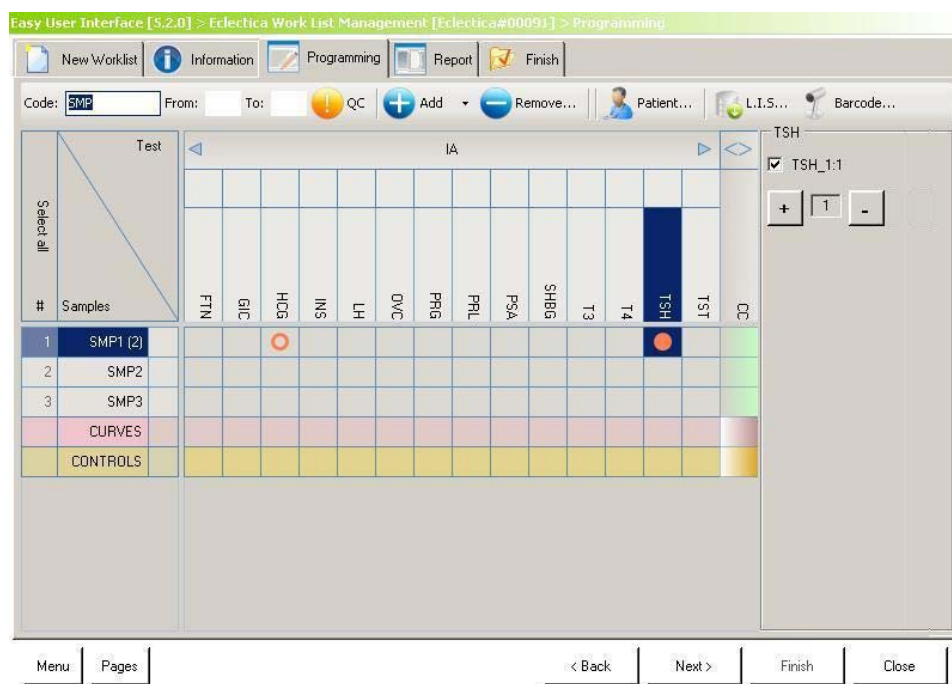


Fig. 7. 50

For all selected methods for which the test can be run on a diluted sample, the Dilution factors window opens to allow the required Dilution factors to be selected (Fig. 7.52)



Fig. 7. 51

The red dot associated with the test can be displayed in two different ways:

- b. **solid red disc** : indicates the selection of all available dilution ratios (even if just one is available, e.g. 1:1)
- c. **red circle** : indicates that only certain dilution ratios have been selected

NOTE: to associate the same method with the most repeated selected samples press one of the following buttons repeatedly  or 

Selection of all samples

- Click on "**SELECT ALL**". All the samples will be selected (Fig. 7. 52)

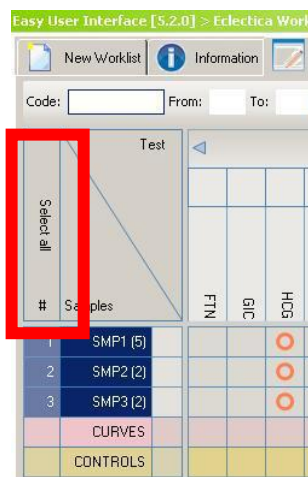


Fig. 7. 52

- Select any cell of the column with the name of the Test to be programmed (the FT3 test in the example of Fig 7.54). A red disc is displayed in correspondence with **ALL** the samples.

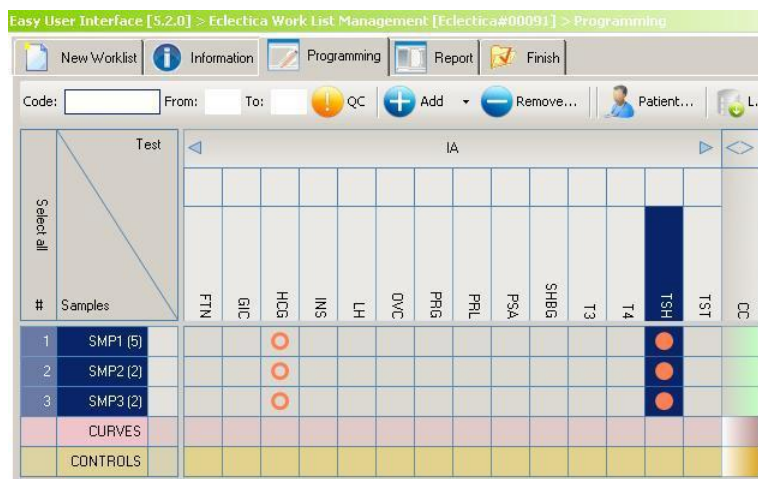
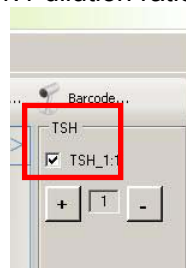


Fig. 7. 53

- To cancel all samples programmed for the selected test uncheck the predilutions box (1:1 dilution ratio):



Deletion of a programmed or entered sample

- Select the row corresponding to the required sample (Fig. 7.54)
- Click on the button 
- Press **Yes** to confirm deletion of the selected sample (Fig. 7. 54)

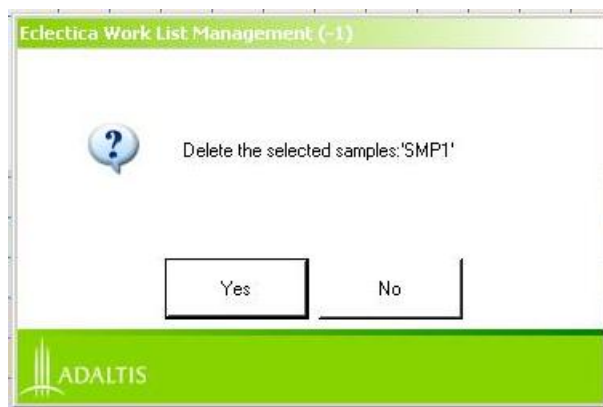


Fig. 7. 54

Entering a sample between two already entered sample IDs:

- In the *Code field* (Fig. 7. 55) enter the sample ID to be input
- Select the line corresponding to the position of the sample required where you want to enter the new sample ID
- Press **Add -> Insert**



Fig. 7. 55

Renaming a sample ID:

- Select the line corresponding to the sample you wish to rename.
- In the *Code field* (Fig. 7. 55) enter the new Sample ID.
- Press **Add - Rename**

Patient Information:

- Select the row corresponding to the required sample



- Press *Patient* to input the patient information corresponding to the selected sample.

A screenshot of the 'Patient Information' dialog box. It contains several input fields: 'Code' (20115001035026), 'Name' (John), 'Second name' (empty), 'Last name' (Smith), 'Sex' (Male), 'Date of birth' (05 March 1968), and 'Description' (Description). There is a large empty text area below the description field. On the right side, there is a graphic of a person in a blue shirt with a stethoscope. At the bottom, there is a green bar with the 'ADALTIS' logo and three buttons: 'OK', 'Cancel', and 'Apply'.

Fig. 7. 56

Quality control programming

- Select the row corresponding to the required sample (Fig. 7. 57)
- Press Quality Control to associate the quality control with the selected sample



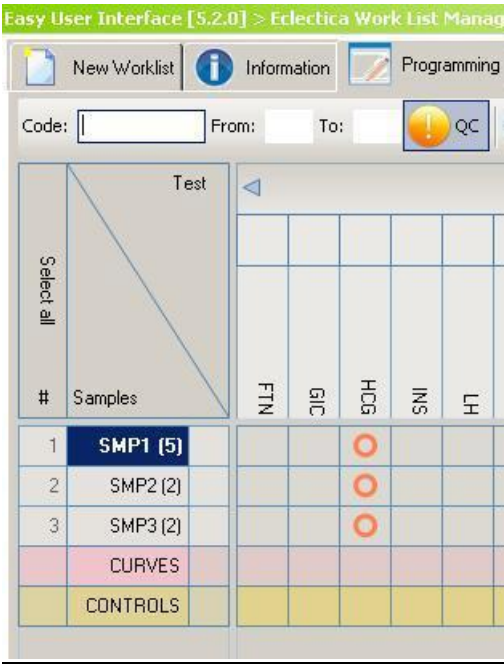


Fig. 7. 57

Automatic samples identification

Press *Barcode...* (Fig. 7. 58)



Fig. 7. 58

for automatic identification of the sample tubes barcodes (Fig. 7. 59).

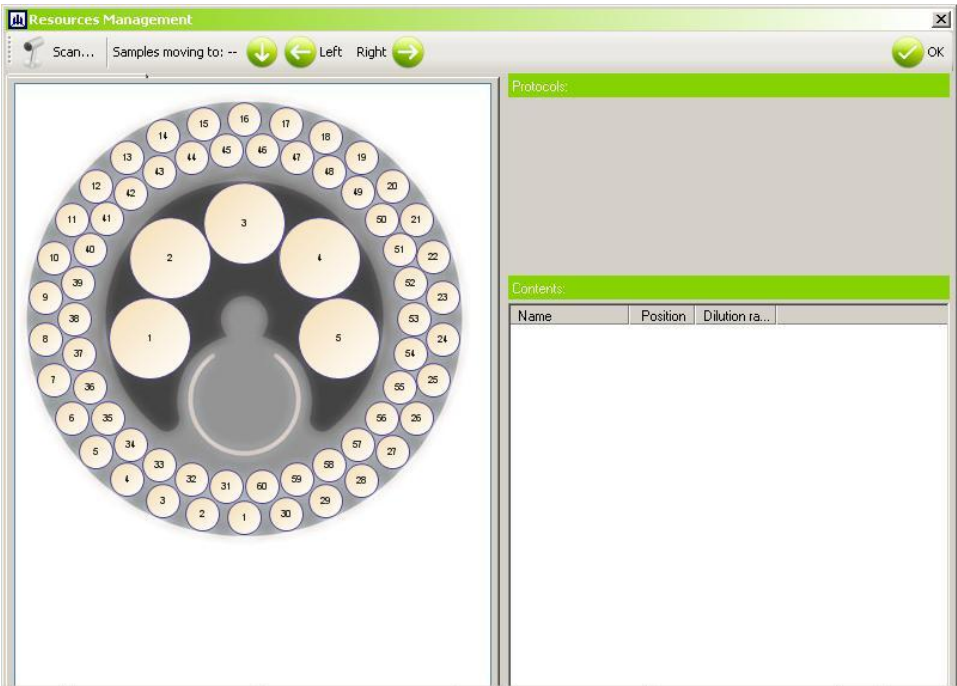


Fig. 7. 59

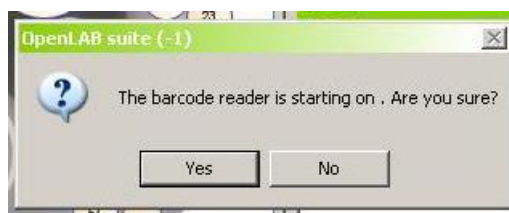


Fig. 7. 60

Select any position on the samples plate with the left mouse button and select **Scan**. A message will be displayed (Fig. 7. 61).

When the sample tubes barcode identification procedure is concluded, the positions of the samples will be automatically associated on the samples plate.

Managing lists from LIS:

Select *L.I.S....* (Fig. 7. 61) to acquire a worklist from the Host (or to retrieve previously executed programming)



Fig. 7. 61

Select the worklist and click on **OK** (Fig. 7. 62)

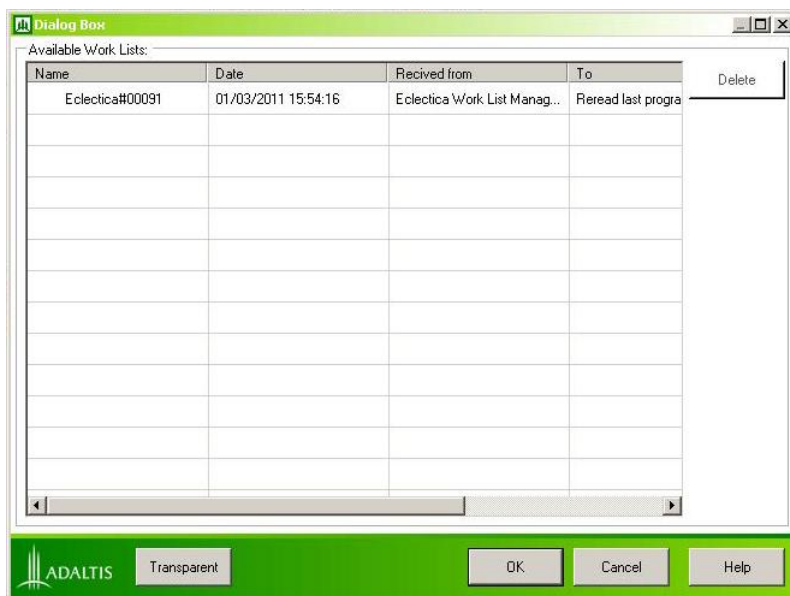


Fig. 7. 62

Add JobList From L.I.S.

JobList information:

Name: Eclectica#00091

Date: 01/03/2011 15:54:16

From: Eclectica Work List Management

To: Reread last programmed Sample P

Test	Count
HCG_500	1
HCG_Pred#50	1
HCG_100	1
HCG_10	1

Samples:

Sample ID	Tests
☒ SMP1	HCG_500; HCG_100; HCG_10; HCG_1; TSH_1;
☒ SMP2	HCG_1; TSH_1;
☒ SMP3	HCG_1; TSH_1;

Select all

Unselect all

ADALTIS

Transparent

OK Cancel Help

Fig. 7. 63

The "Joblist information" box (Fig. 7. 63) gives general information on the worklist to import and the total number of tests programmed in it

The "Samples" box shows the samples and tests programmed in the worklist to be imported

- A tick is displayed on the samples programmed in the current worklist.
- The tick is not shown for samples that are not programmed in the current worklist.



WARNING: In the case of acquisition from barcodes, it is important to perform automatic samples identification before uploading the worklist.

Report of the programmed worklist

The **Report** section display a detailed report of the programmed worklist (Fig. 7. 64)

Easy User Interface [5.2.0] > Eclectica Work List Management [Eclectica#00092] > Report

New Worklist Information Programming Report Finish

Back Next Home Print Preview... Print...

Work List Report

Company: ADALTIS S.r.l.

Date: 01 March 2011

Work List n. Eclectica#00092

Author: User

Instrument sn: Eclectica001

Sample	Patient	Number of replicates	Method	Dilution	Quality Control
SMP2		1	HCG	1:1	
SMP2		1	TSH	1:1	
SMP3		1	HCG	1:1	
SMP3		1	TSH	1:1	
Number of programmed test		4			

Signature _____

Menu Pages < Back Next > Finish Close

Fig. 7. 64

Sort by Patient:

To arrange patients in alphabetical order, click on the **Patient** label (shown in the red box Fig. 7. 64)

Easy User Interface [5.2.0] > Eclectica Work List Management [Eclectica#00092] > Report

New Worklist Information Programming Report Finish

Back Next Home Print Preview... Print...

Work List Report

Company: ADALTIS S.r.l.

Date: 01 March 2011

Work List n. Eclectica#00092

Author: User

Instrument sn: Eclectica001

Sample	Patient	Number of replicates	Method	Dilution	Quality Control
SMP2		1	HCG	1:1	
SMP2		1	TSH	1:1	
SMP3		1	HCG	1:1	
SMP3		1	TSH	1:1	
Number of programmed test		4			

Sort by Test:

To arrange the Tests in alphabetical order, click on the **Method** label (shown in the red box Fig. 7. 64)

Easy User Interface [5.2.0] > Eclectica Work List Management [Eclectica#00092] > Report

New Worklist Information Programming Report Finish

Back Next Home Print Preview... Print...

Work List Report

Company: ADALTIS S.r.l.

Date: 01 March 2011
Work List n.: Eclectica#00092
Author: User
Instrument sn: Eclectica001

Sample	Patient	Number of replicates	Method	Dilution	Quality Control
SMP2		1	HCG	1:1	
SMP2		1	TSH	1:1	
SMP3		1	HCG	1:1	
SMP3		1	TSH	1:1	
Number of programmed test		4			

Sort by Sample:

To arrange the Samples in alphabetical order, click on the **Sample** label (shown in the red box Fig. 7. 64)

Easy User Interface [5.2.0] > Eclectica Work List Management [Eclectica#00092] > Report

New Worklist Information Programming Report Finish

Back Next Home Print Preview... Print...

Work List Report

Company: ADALTIS S.r.l.

Date: 01 March 2011
Work List n.: Eclectica#00092
Author: User
Instrument sn: Eclectica001

Sample	Patient	Number of replicates	Method	Dilution	Quality Control
SMP2		1	HCG	1:1	
SMP2		1	TSH	1:1	
SMP3		1	HCG	1:1	
SMP3		1	TSH	1:1	
Number of programmed test		4			

End

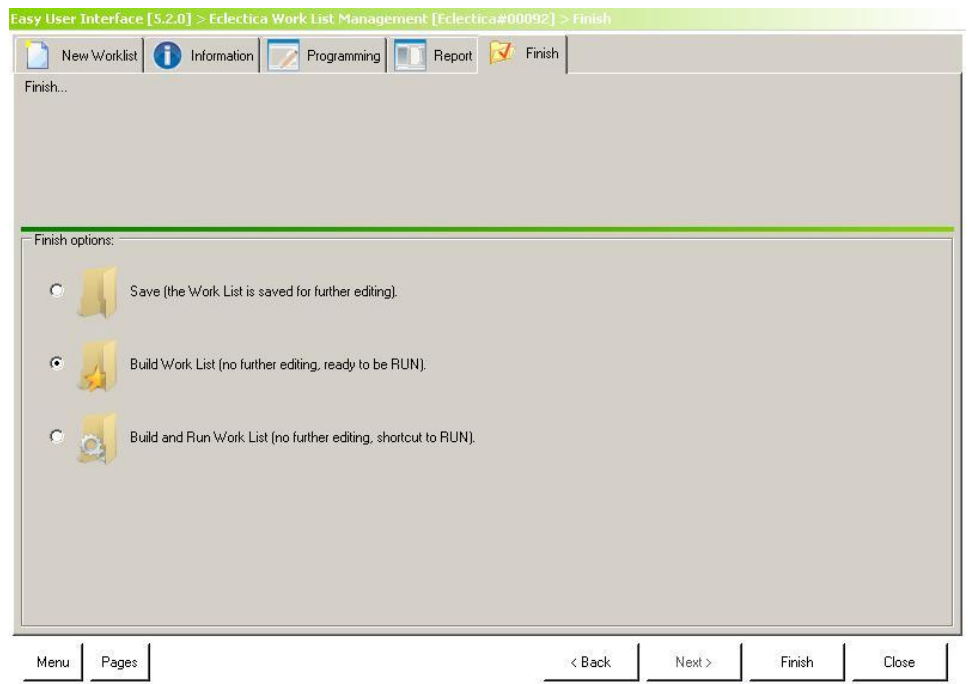


Fig. 7. 65

Once the worklist programming procedure is concluded, in the *Finish* page the user can select one of the following three options (Fig. 7. 65):

- **Save:** The programmed worklist can be edited and it is not yet displayed in the list of worklists ready to be executed
- **Build worklist:** The worklist can no longer be edited. It is only executable and it will be displayed in the list of Worklists ready to be executed
- **Build and Run worklist:** The worklist is saved, built (closed) and clicking on the **"Finish"** button will send you directly to the worklists execution module (WLE: see next section - *Execution of a worklist*).

Executing a Worklist

The OpenLAB ECLECTICA™ management software envisages processing of the resources required for execution of the programmed worklist, uploading, and subsequent execution of the worklist.

From the Main Menu page, press the *Eclectica Worklist Execution* icon (Fig. 7. 66)

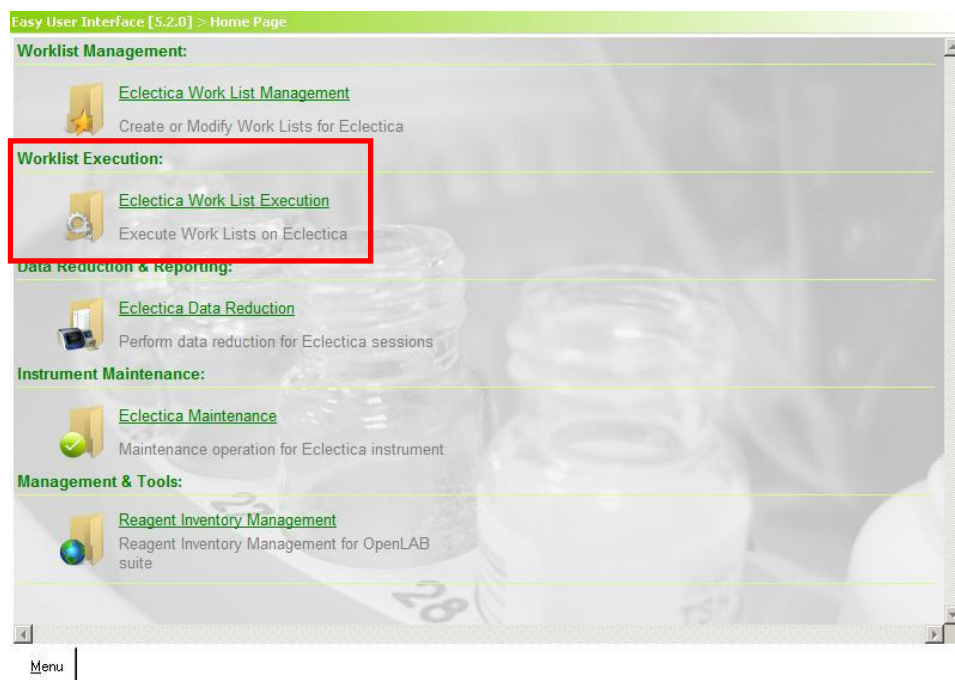


Fig. 7. 66

Selection of the worklist to be executed

In the **Open WorkList** page (Fig. 7. 67) select the following options:

- Execute a pending worklist
- Execute a programmed and saved worklist,

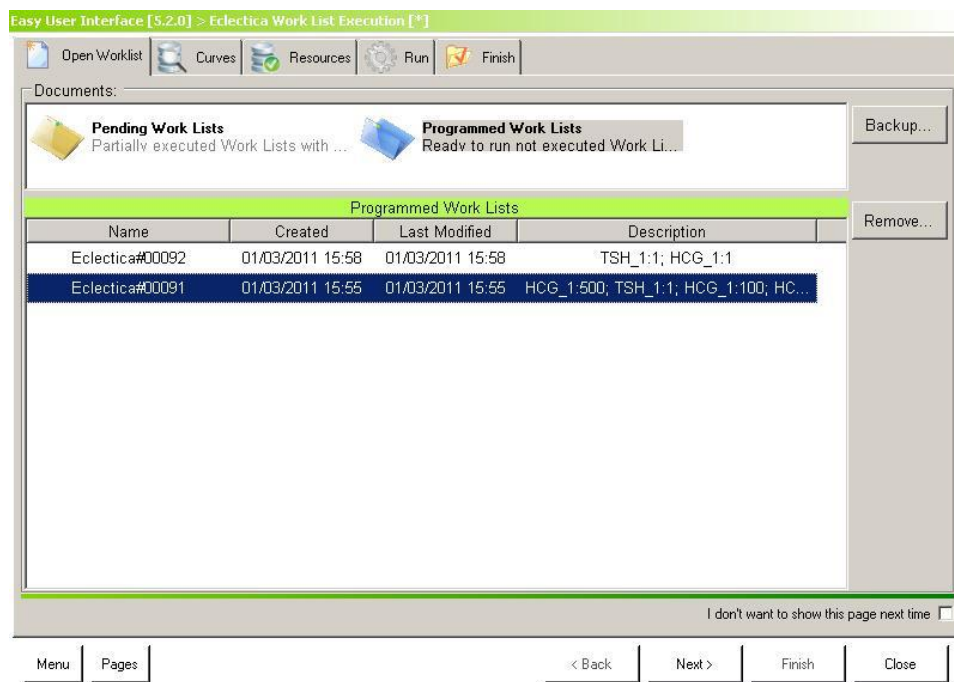


Fig. 7. 67

Selecting the following option: (Fig. 7. 68):

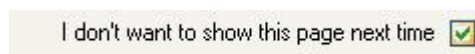


Fig. 7. 68

the current page (Fig. 7. 67) is not displayed at the next start of the execution module.

Click **Next** to go to the next page.

Execute a programmed Worklist

In the **Open WorkList** page (Fig. 7. 67) select *Programmed Work Lists*.

NOTE: the selected worklist may involve execution of samples only, samples and C1 and C2 Controls, samples, C1/C2 and standardizations for one or more tests.

Click on **Next** to go to the *Curve* section.

Managing pending lists

If certain of the tests associated with the samples are not performed during execution of a worklist, the software will notify the user that the job has not been completed and will set the list to "pending" status. When a "pending" list is reopened subsequently, the facility will be provided to conclude the previously uncompleted tests.

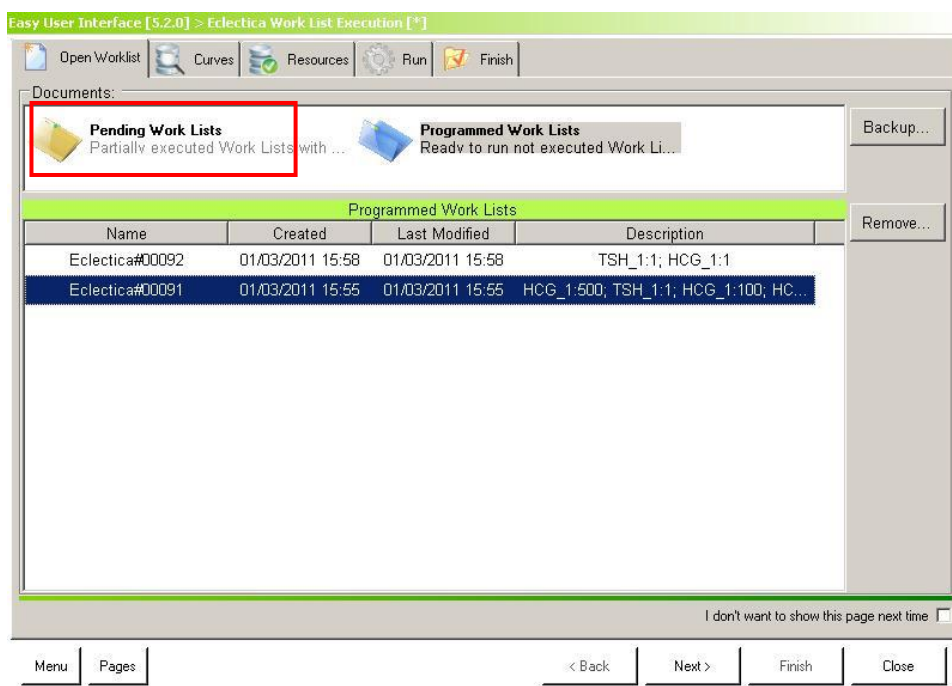


Fig. 7. 69

Start the module relative to worklists execution, select the *Pending WorkList* option (Fig. 7. 69) and select the pending worklist containing tests not yet executed

When processing is terminated the only tests that will be executed are those that were previously not completed.

NOTE: the lot of specific reagents that will be utilised in execution of the pending list **MUST ALWAYS** be the same as that selected in the previous stage (execution of source worklist).

Curves: Calibration curves management

In the **curves** page (Fig. 7.71) the state of every single calibration curve used to determine the analytical results and generated by the mastercurve or by a standardization routine is displayed (see: "*Calibration method for Immunoassay*" in Section 4: "*Operating principles*").

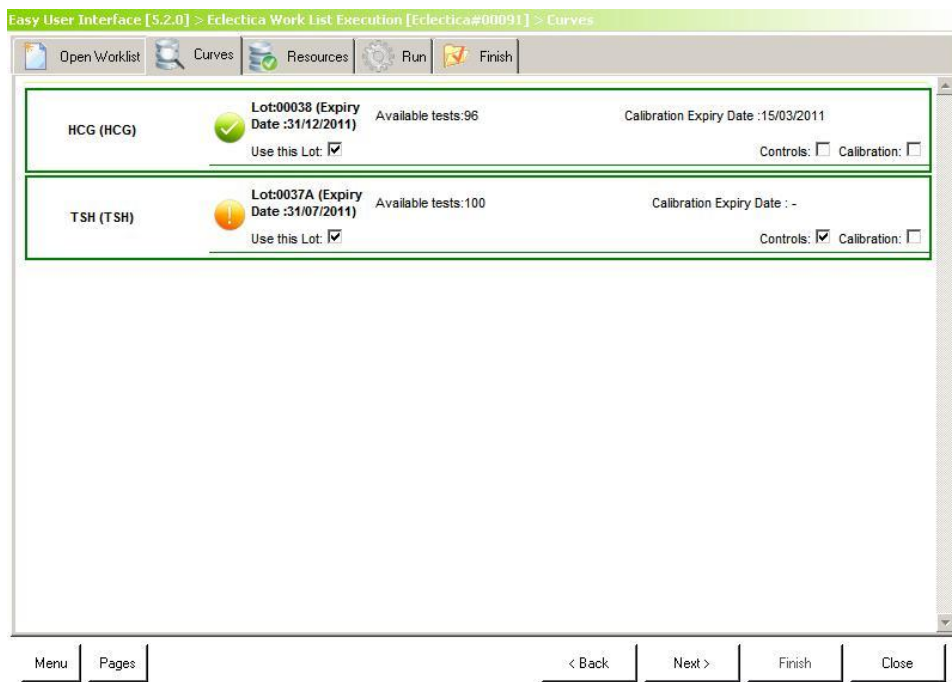
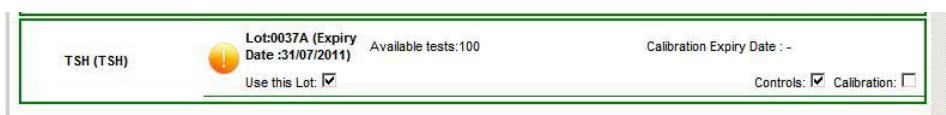
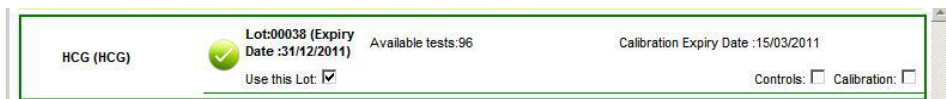


Fig. 7. 70

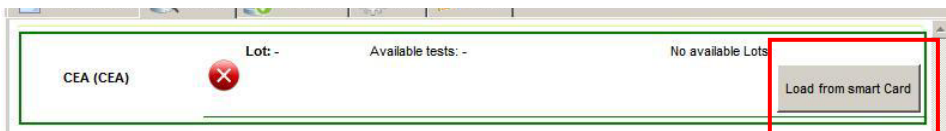
The figure shows an example relative to two programmed tests, the lots of which are valid, but it is necessary to execute controls C1 and C2 for the HCG test(immunoassay) and standardization (Curve) for the clinical chemistry test (glucose). All the lots loaded for each analyte and their status are also displayed. The various options are summarised below:



In this case it is necessary to execute controls of a curve (*Calibrators* option selected) or standardization (*Curves* option selected). If several lots have been loaded on the analyzer, you can select which lot you wish to use in the current worklist (selecting the *Use this Lot* option in correspondence with the chosen lot)



In this case the lot is valid and that calibration does not call for any further action (none of the *Calibrators* or *Curve* options are checked)



In this case no lot relative to the test to be executed is loaded on the analyzer. Click on *Load from Smart Card* to load the relative Smart Card.

NOTE: If a calibration curve and/or controls are programmed beforehand directly during programming of the worklist (refer to *Programming a Worklist*), a tick symbol will be displayed on the selected option irrespective of the calibration status.

NOTE: For all the tests (IA, CC) execution of calibration checks is optional if a valid (even though expired) calibration curve exists (a mastercurve without any previous check is not a valid curve).

NOTE: Refer to section 4 "Calibration method for Immunoassay" for further information on management of the calibration curves.

Press **Next >** to go to the **Resources**

Resources

Resource Manager automatically checks the availability of the necessary resources (Specific Reagents, Controls, Calibrators, Diluents, Common Reagents, Wash Solution) at the time of execution of the planned tests and provides the user with specific notification messages relative to the problem(s) encountered, if any (Fig. 7. 71).

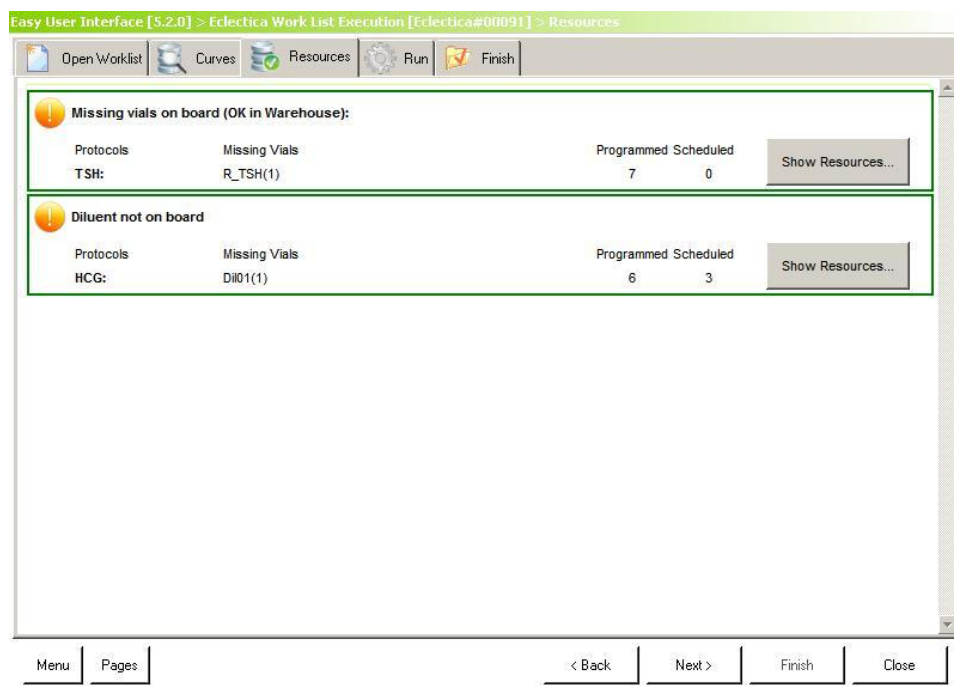


Fig. 7. 71

If the daily Start Up procedure has not been performed, you will be prompted to open the Maintenance section to launch the Start Up

If the resources on board are sufficient all the programmed tests will be executable.

If the resources on board are insufficient specific warning messages will be displayed prompting the user to:

- Load Specific Reagents
- Load Controls for all the programmed tests requiring the execution of controls C1, C2
- Load Calibrators for all the programmed tests requiring standardization.
- Load samples
- Load Common Reagents
- Load Diluents

The User can anyway execute only those tests in relation to which the resources loaded on board the system are sufficient; non-executable tests will result in a "pending" list (see Section *Management of pending lists*).

Resource Manager is opened by clicking the *Show Resources* button and it shows the reagents plate (Fig. 7. 73) and the sample carousel.

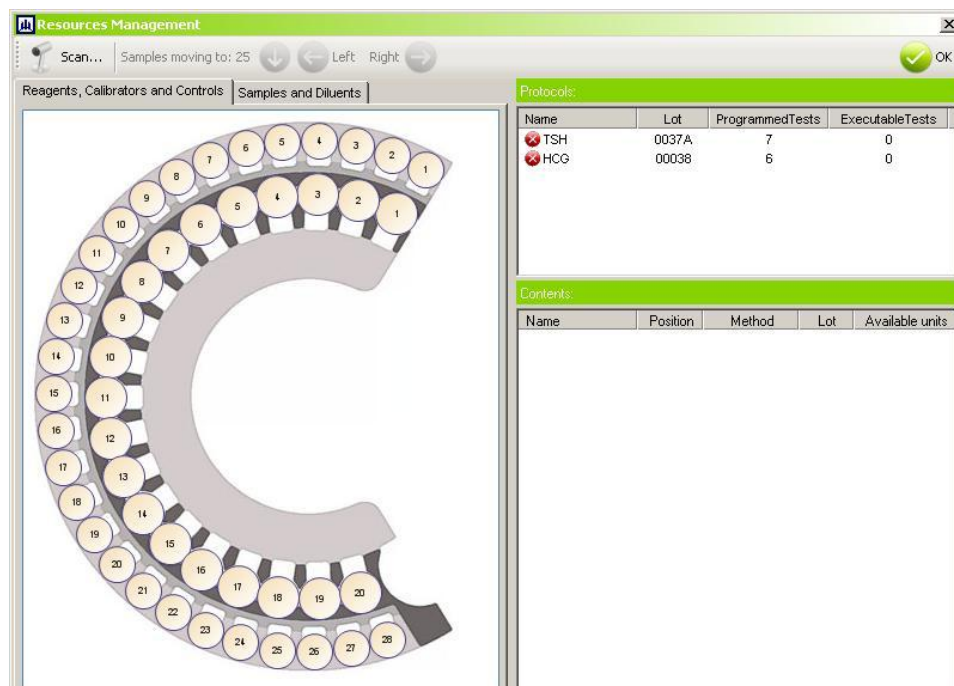


Fig. 7. 72

To allocate a reagent proceed by using the bar codes or manually.

Barcode:

position the vials on the respective rings in the reagents carousel (no specific order required), ensuring the barcodes are facing the centre of the ring. Select the ring you wish to acquire (reagents or controls) and then click on the *Scan* button at the top left of the screen (fig. 7.73). The following pop-up window will appear (e.g. in the case of reagents):



Fig. 7. 73

Click on Yes and wait for the automatic procedure to terminate.

Manually:

Left click on the required position of the ring of controls or reagents and select the operation to be performed from among those displayed by the popup window that is displayed (Fig. 7.75 and following).

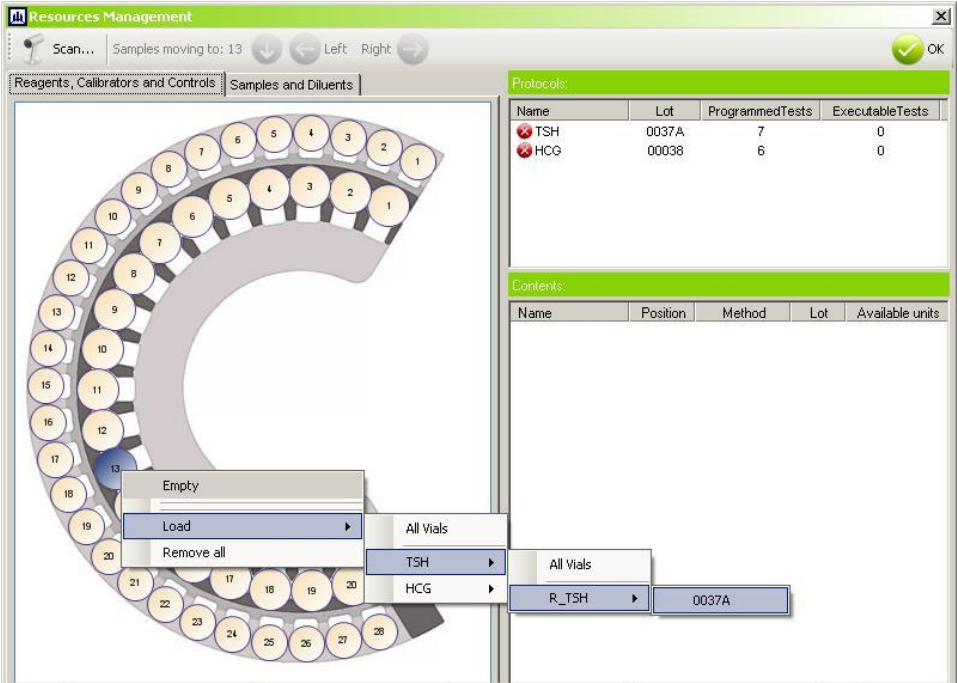


Fig. 7. 74: Loading reagents

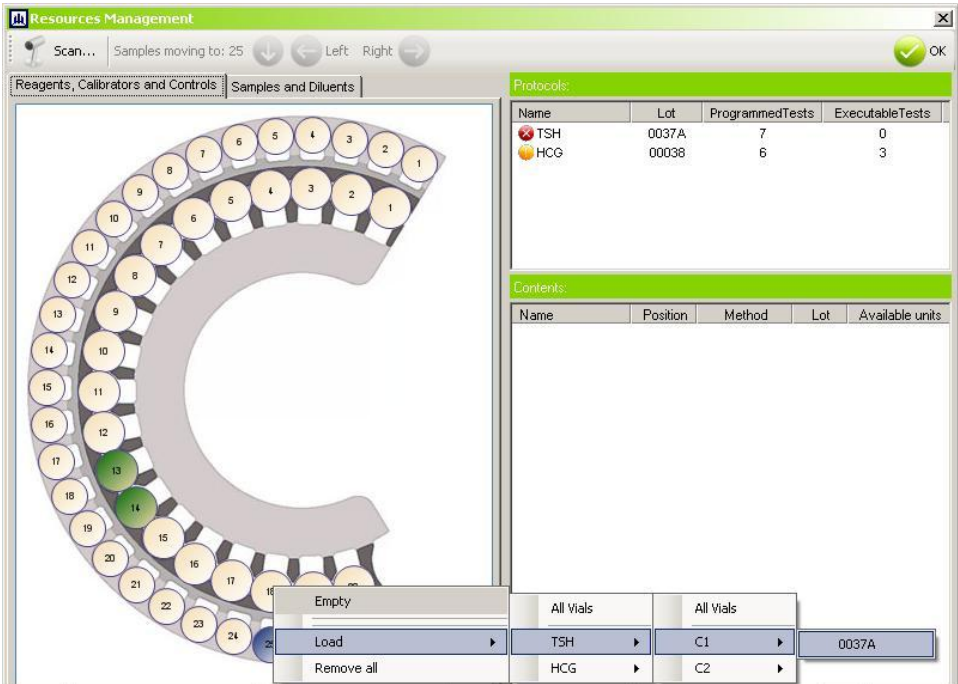


Fig. 7. 75: Loading controls

Once loading procedures are completed, the contents of each position can be specified by clicking on it with the left mouse button (Fig. 7.77). Also the available tests for the selected vial will be highlighted.

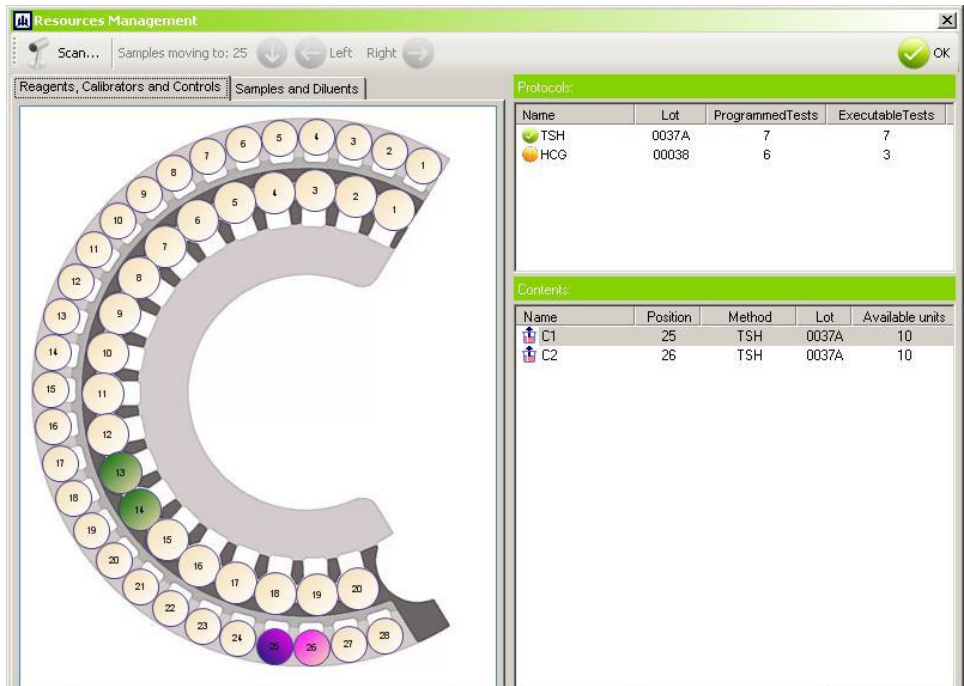


Fig. 7. 76

The following table provides an overview of all the commands selectable from the menu

Command	Description
Load	Loading Reagents/Controls/Calibrators on reagents/samples carousel Select the required position on the plate with the left Load button. The following menus assist the User in choosing the most appropriate components
Load->All vials	Loading all reagents/controls in sequence on the samples carousel starting from the selected position
Load->Analyte->All vials	Serves to load all vials associated with a specific test
Load->Analyte->Vial code	Serves to load only one type of vial (in the case of reagent kits)
Replace	Replace the contents of a given position with a different component
Remove	Remove the previously allocated reagent or control
RemoveAll	Remove all previously allocated reagents or controls
Move	Move the vial from one position to another
Discard	Discard a vial and its contents. The number of tests available for the discarded resource is consequently decreased.

Loading Samples:

The **SamplePlate** page (Fig. 7. 77) displays the samples carousel.

The following information is given for each sample (*Contents*):

- in the *Name* field
- in the *Position* field: the position assigned in the Samples Carousel,

The following information is given for each protocol (*Protocols*):

- Test name
- Lot
- Number of programmed tests
- Executable Tests

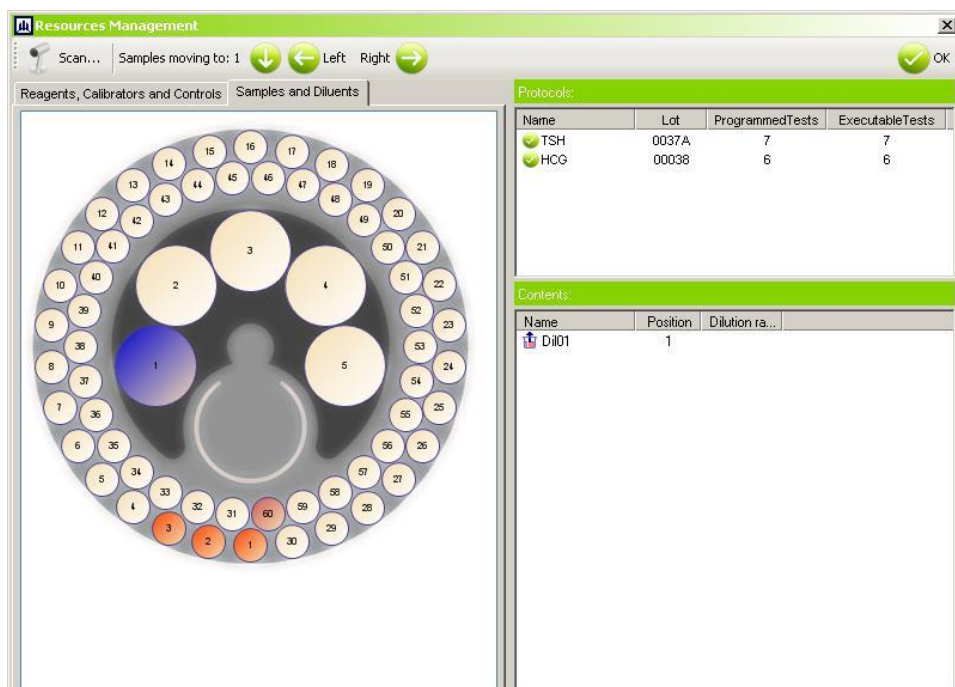


Fig. 7. 77

Automatic loading:

If the *Automatic Sample Allocation* parameter in the *options* has been set to True (Refer to the heading: *Additional Functions*), the samples will be loaded automatically on the carousel in a sequential position.

Manual loading:

To load all the samples in sequence on the samples carousel starting from the selected position of the plate, click on **Load-> All samples** with the left mouse button (Fig. 7. 78)

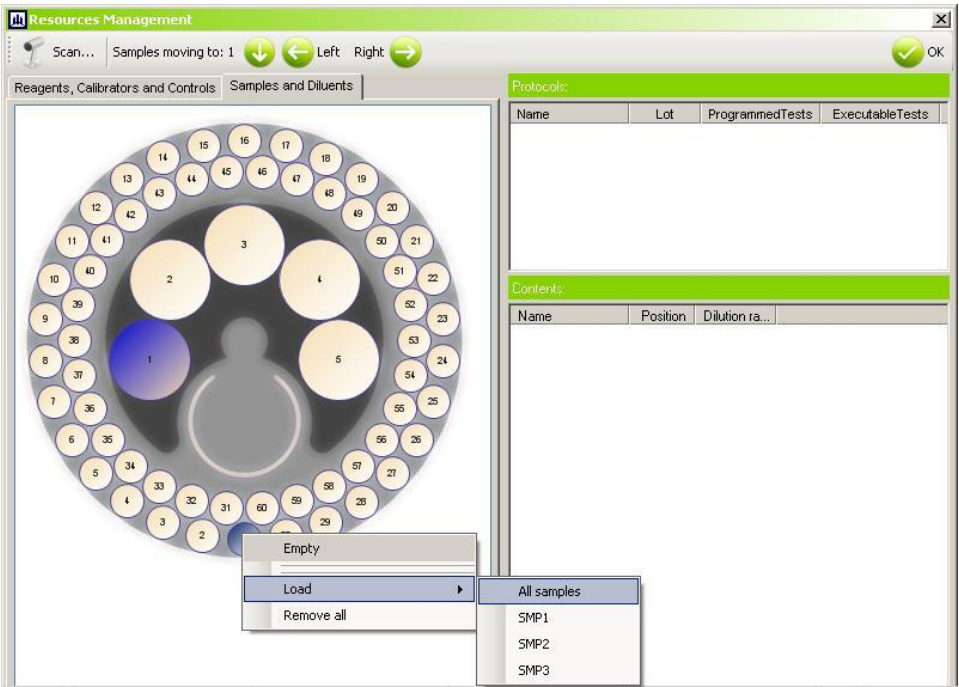


Fig. 7. 78

At the end of the procedure, the screen will show the position of each sample and the programmed tests to be executed.
If samples with dilution are programmed, the positions of the undiluted samples will be displayed and also the empty tubes to be inserted for dilution (starting from position 60):



WARNING: To avoid damages it's VERY important to load sample/empty tubes where required by the software.

Loading Diluents:

Load the bottles of Diluent in the special wells located at the centre of the Samples Carousel, left clicking the mouse on the required Samples Carousel position and selecting **Load->dil**

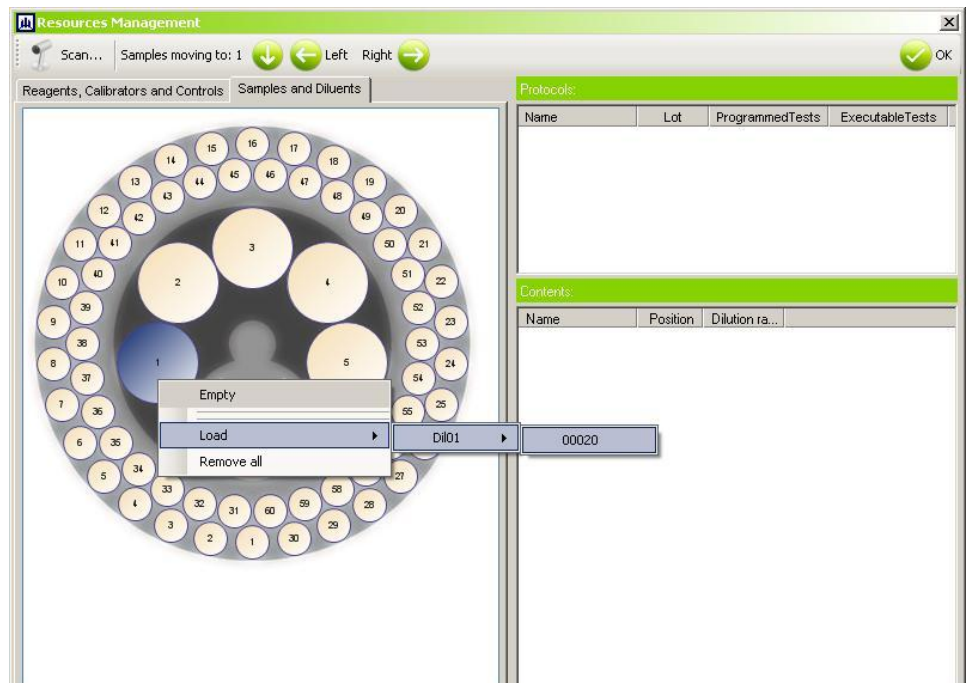


Fig. 7. 79

Select **Ok** to continue

Automatic samples identification

Click on *SamplePlate* tab, select one position on the sample carousel and then click on the *Scan* button (Fig. 7. 80) for automatic identification of the samples loaded on the samples plate



Fig. 7. 80

Loading Common Reagents

Refer to Section 8: Maintenance: *Replacing and Loading the Common Reagents*

Run

The **Run** page (Fig. 7. 81) will display the list of tests to be executed and indicate the estimated execution times for individual tests and for the entire worklist. If the number of tests to be executed is higher than the available number of reaction cells, the list will be divided into several runs (although it will continue to be a single list).

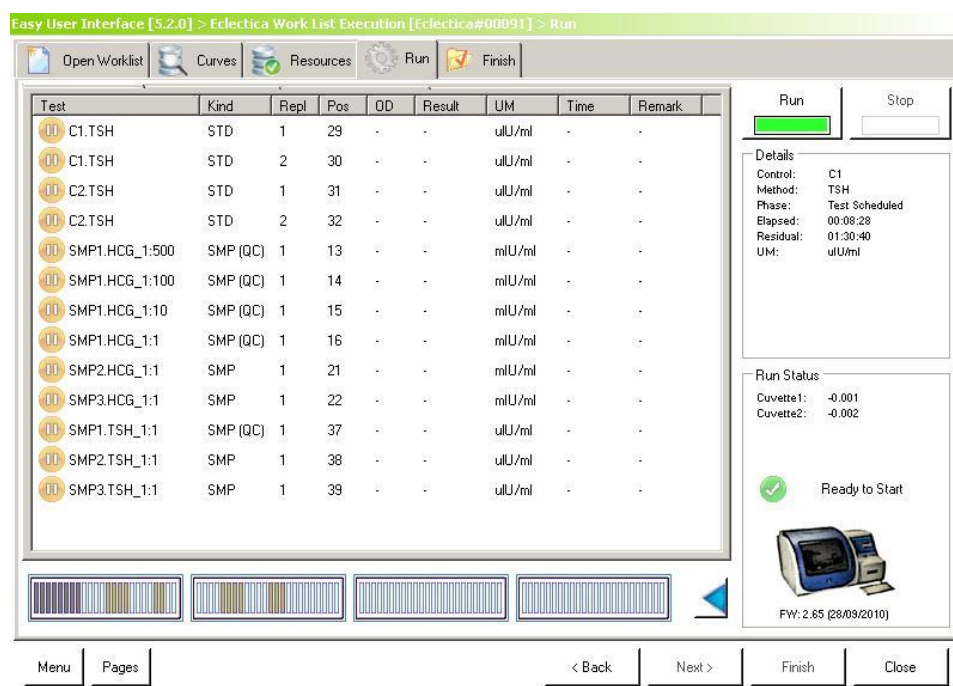


Fig. 7. 81



WARNING: On entering the page, the software performs an automatic volumes check (with the level sensor) of: diluents, CC calibrators and specific reagents, only if contained in multiple vials. Any anomalies are indicated to the user by suitable messages that will assist in solving the relative problem.

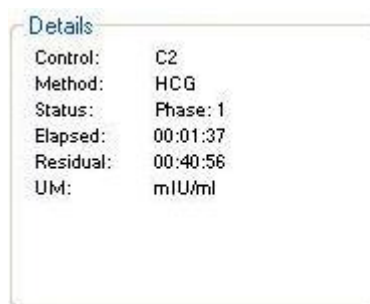


WARNING: Before pressing *Run* make sure the 4 Reaction Segments have been inserted in the specific wells. For the procedure for inserting the Reaction Segments, see: "Changing the Reaction Segments" in Section 8: "*Maintenance*".

During execution of the worklist the *Execution page* will update the following in real time, by means of information provided in specific fields:

- tests status (programmed, not programmed, reaction cell not available, running, completed),
- test results obtained (absorbance and concentration)
- values of Blanks 1 and 2 (IA)
- Execution errors, if present
- Unit of measurement

The details relative to the individual test selected are shown in the *Details* box at the top right of the page:

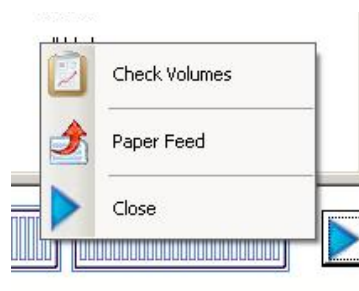


The reaction segments are shown at the bottom of the page; cells that cannot be used are shaded.

To replace segments simply click on the relative symbol and follow the instructions.



Click on the right of the segments representation to open the menu shown in the following screenshot:



This menu provides the facility to perform the operations specified in the following table:

Command	Description
Check Volumes	Provides the facility to manage the volumes check of the components loaded on board
Paper Feed	Feeds the paper of the internal printer.
Close	Closes the menu

NOTE: during execution of the worklist the test results obtained are printed automatically using the internal printer installed in the instrument.

NOTE: you can abort execution of the current worklist at any time by pressing the *Stop button* (Fig. 7. 82), which is displayed in red during execution.

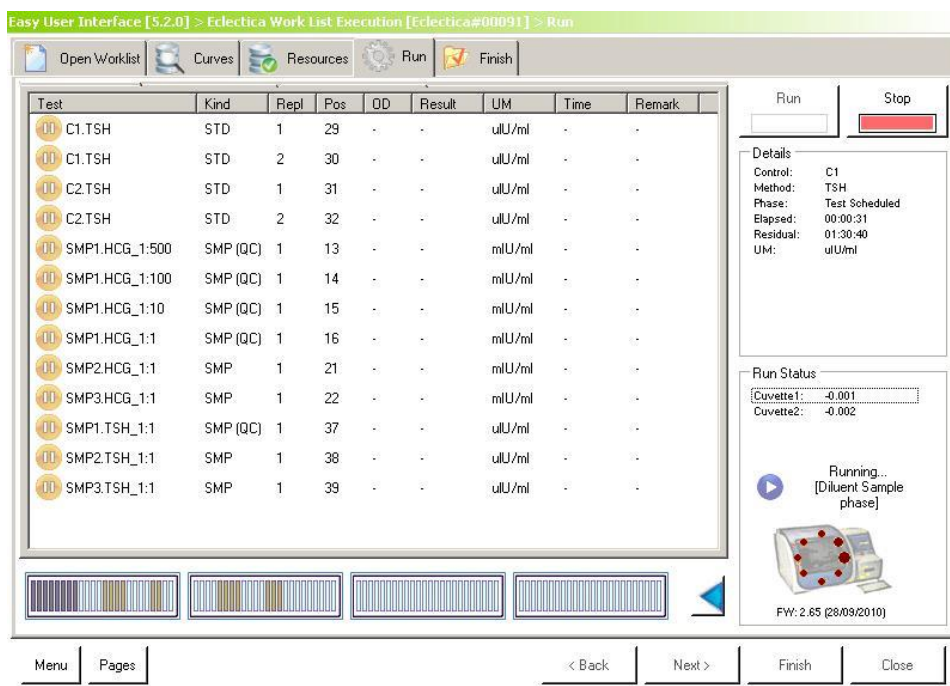
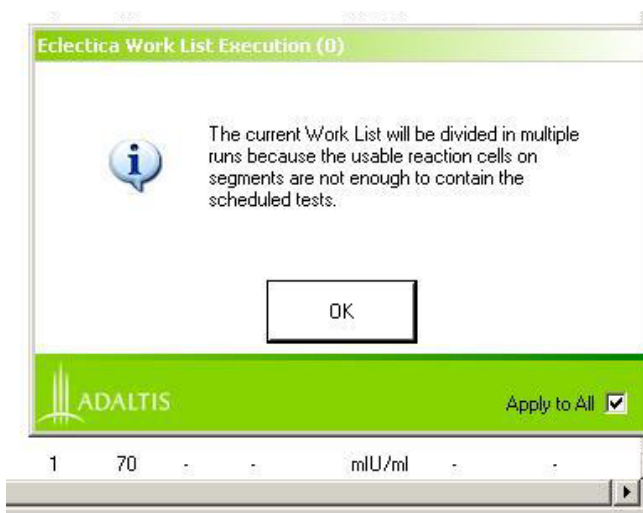
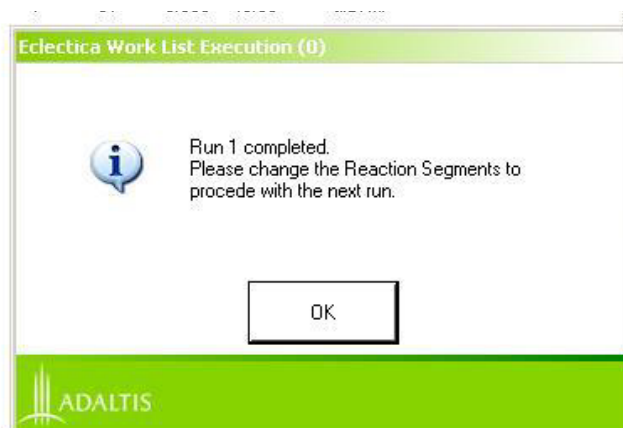


Fig. 7. 82

If the list is divided into several runs, at the beginning of the first portion of the list the following message is displayed:



At the end of the first portion, the following message will appear:



After replacing the segments with a new set, you can resume execution of the worklist.

The meaning of the symbols beside each test/sample during the run is

-  Sample/test waiting for execution
-  Sample/test being executed
-  Sample to be executed in the second portion of the list
-  Sample/test successfully executed

When worklist execution has been completed, the execution end message will be displayed (Fig. 7. 83).

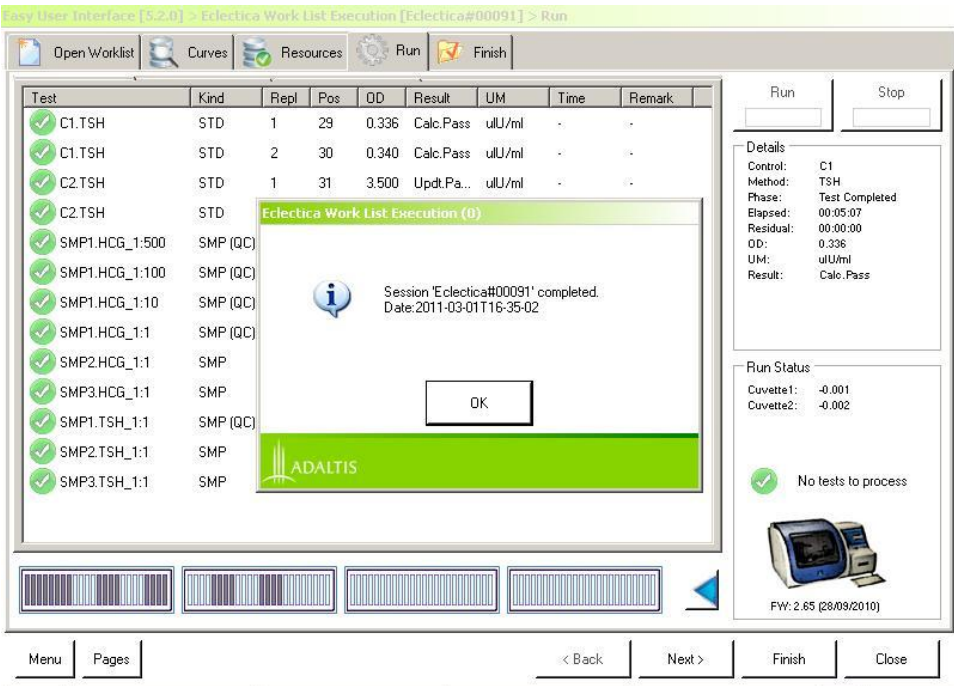


Fig. 7. 83

Execution end

In the *Finish* section (Fig. 7. 84) the following options are possible:

- Select "*Accept and save results*" to save and display the worklist in the list of sessions executed in the section *Viewing and printing the results for a worklist*.
- The second option makes it possible to launch the results processing plug-in (data-reduction) immediately

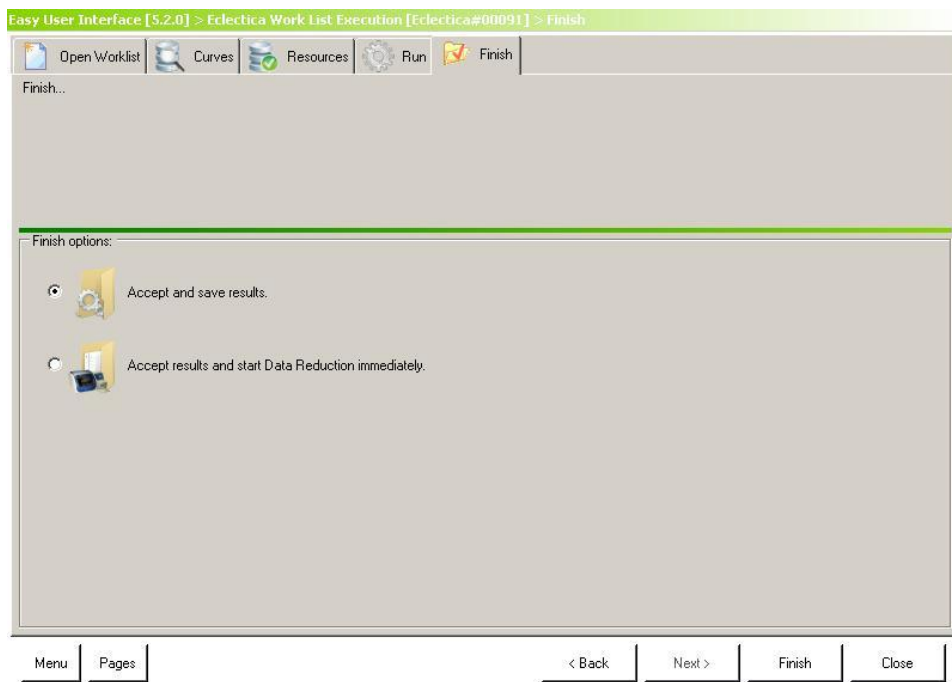


Fig. 7. 84

NOTE: if at least one of the tests associated with one or more samples is not performed during execution of a worklist, the user can leave the tests/controls in the current pending list which, after re-processing, will result in execution of only those tests/controls that were not completed previously.

For all tests associated with possible controls that are found to be outside the limits of acceptability, it will also be possible to calculate the result after repeating and accepting the controls within the following 24 hour period.

For correct management of partially executed worklists, see: "*Management of partially executed lists*" in this Section.

Viewing and printing the results of a worklist

The OpenLAB ECLECTICA™ software allows the test results of an executed worklist to be displayed and printed.

Press the ***Eclectica Data Reduction icon*** on the *Main Menu* page. to enter the section reserved for results processing and printing

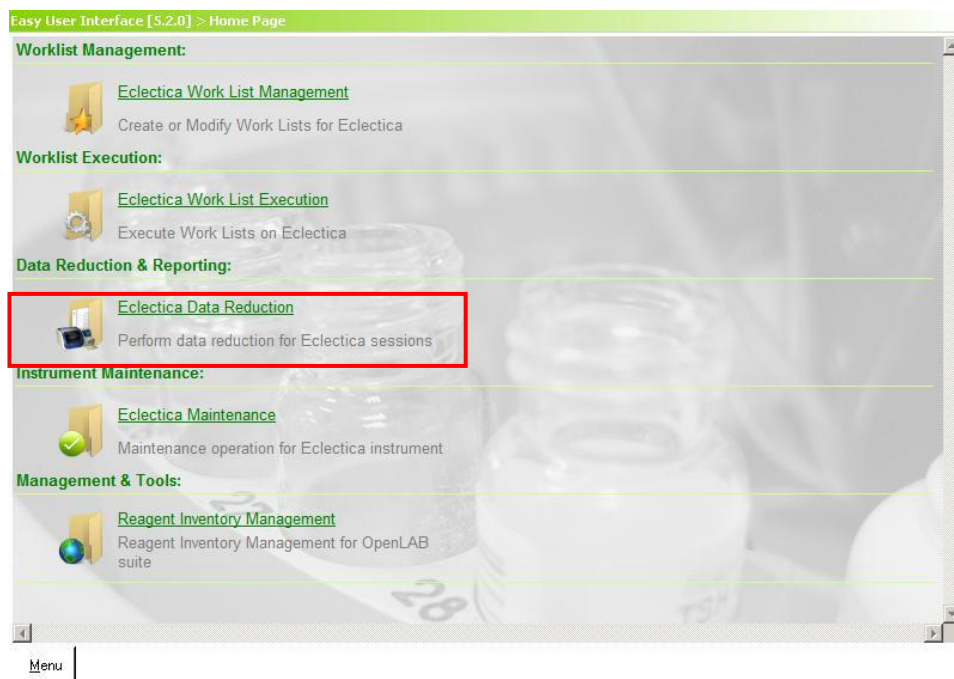


Fig. 7. 85

Selecting a Worklist

The **Select Session** section (Fig. 7. 86) allows the user to print the results of both saved worklists and lists in execution for completed protocols.

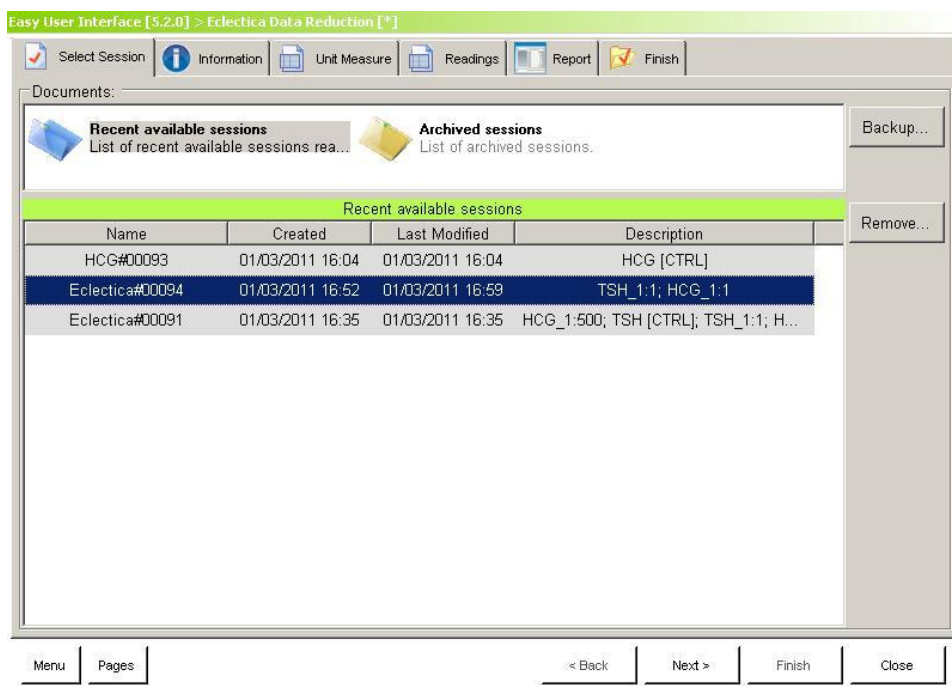


Fig. 7. 86

- Select *Recent Available sessions option* (Fig. 7. 86) and select a previously programmed worklist.
- Press **Next** to process the results: in the *Information* you can find a brief description of the worklist (Fig. 7.46)

NOTE: the lists in the archive (**Archived sessions**) are executed and already reported lists.

Unit of Measurement

In the **Unit Measure** section (Fig. 7.88) the user can change the normal values of a test and set the unit of measurement that will be used to present the results of the tests performed.

Selecting the Unit of measurement (example):

- select the **mlU/ml** button to open a menu showing the selectable units,
- select the unit of measurement required for each method, in the *Used UM column*;

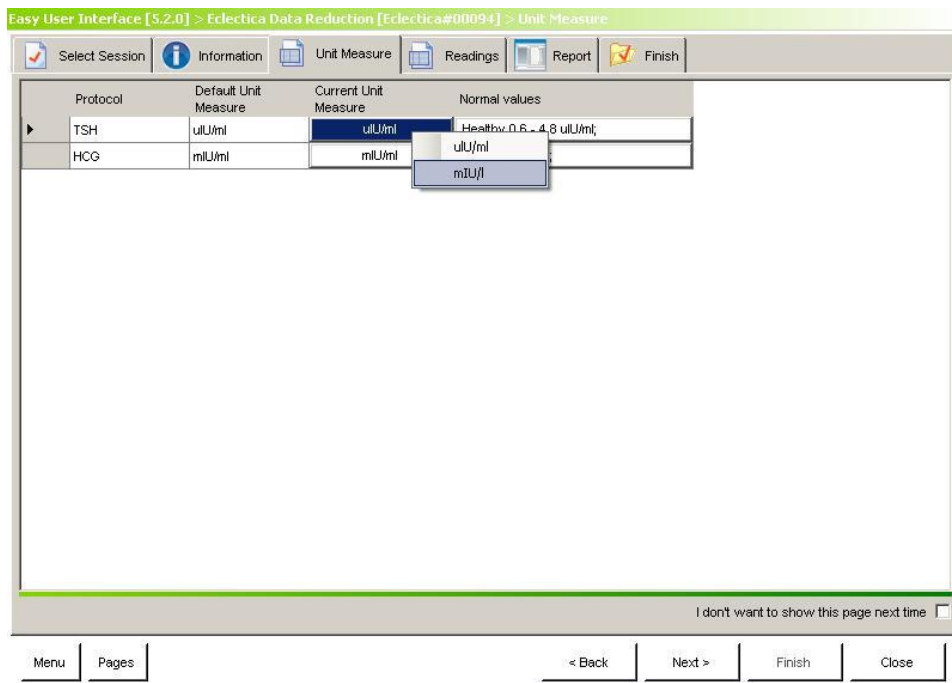


Fig. 7. 87

Editing the Normal value:

- select the method and press the corresponding button in the **Normal values** column
- to add or remove a field, click on **Add** or **Remove** button

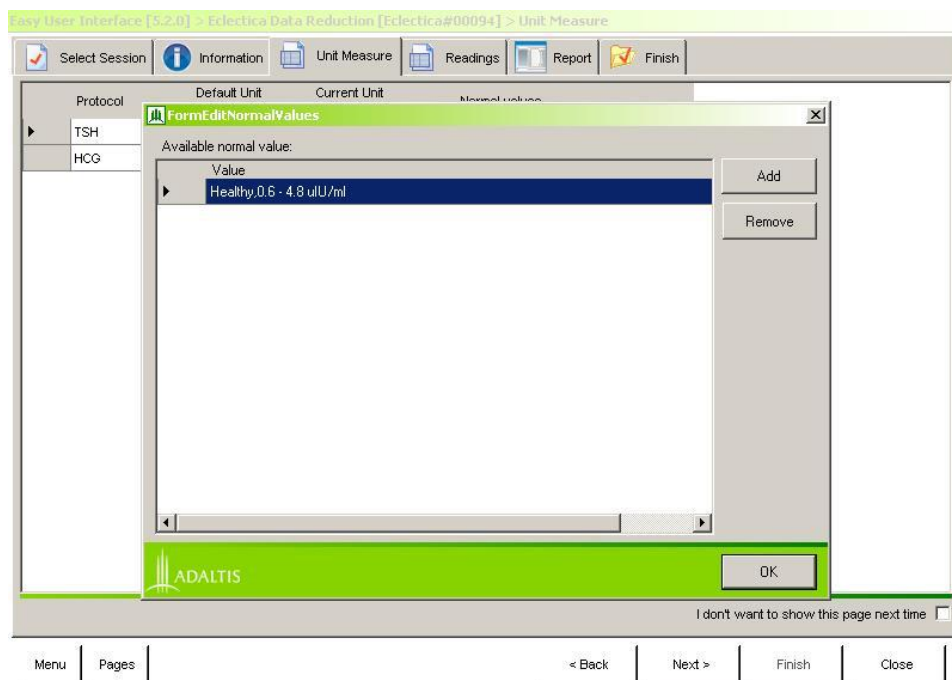


Fig. 7. 88

- Enter the Description and the corresponding Normal value and press **OK** to confirm (Fig. 7.89)

Reading

The **Reading** section (Fig. 7. 89) displays the raw optical density values read by the photometer for each protocol.

The green flag to the left of the test names indicates that the raw test data are available for results calculation

Select the tests for which you require an assessment of the results in the *Test list*.

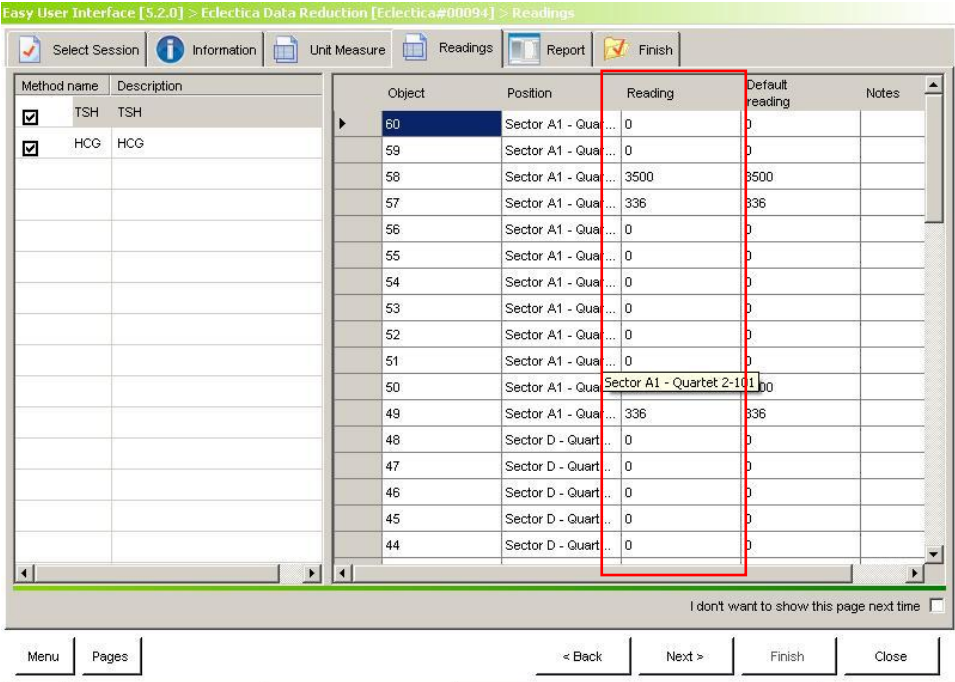


Fig. 7. 89

Reports

The report relative to the worklist executed (Fig. 7. 90) shows an index with the list of the evaluated tests.

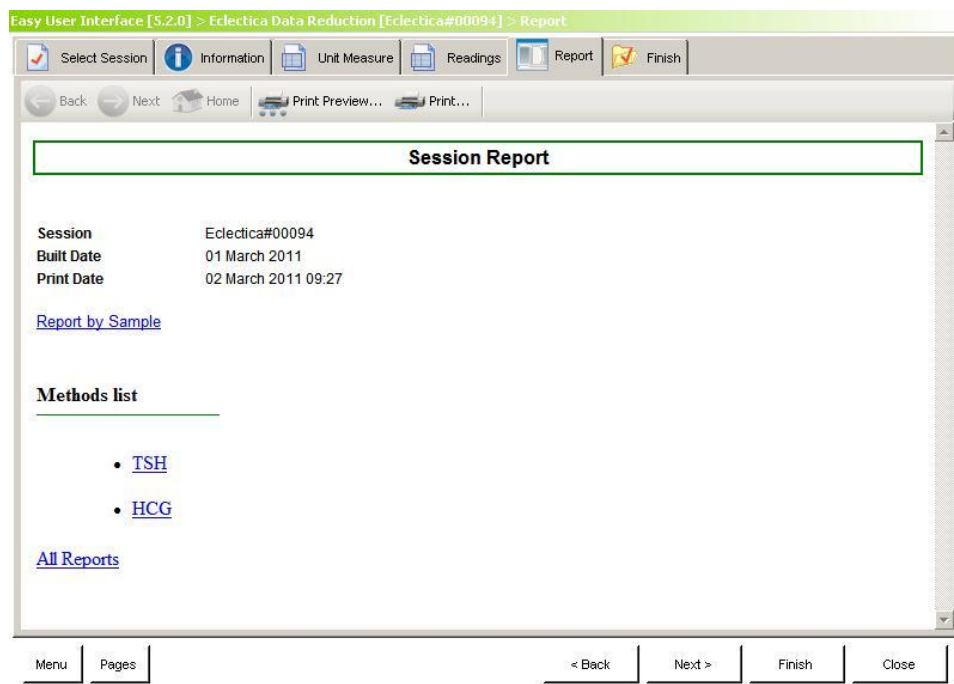


Fig. 7. 90

Two types of report can be selected:

- Report by single method
- Report by patient
- All reports: shows the reports for all the programmed methods in the same window (scroll down to see them)

Report by single method

Select one of the methods listed (Fig. 7. 90) to display the report of the worklist executed on the selected method and to print it on the external printer.

NOTE: if the external printer is not on line, or if the user so requires, it is possible to obtain a simplified version of the report using the internal printer, after configuring the software appropriately (see *"Additional Functions"* in this Section)

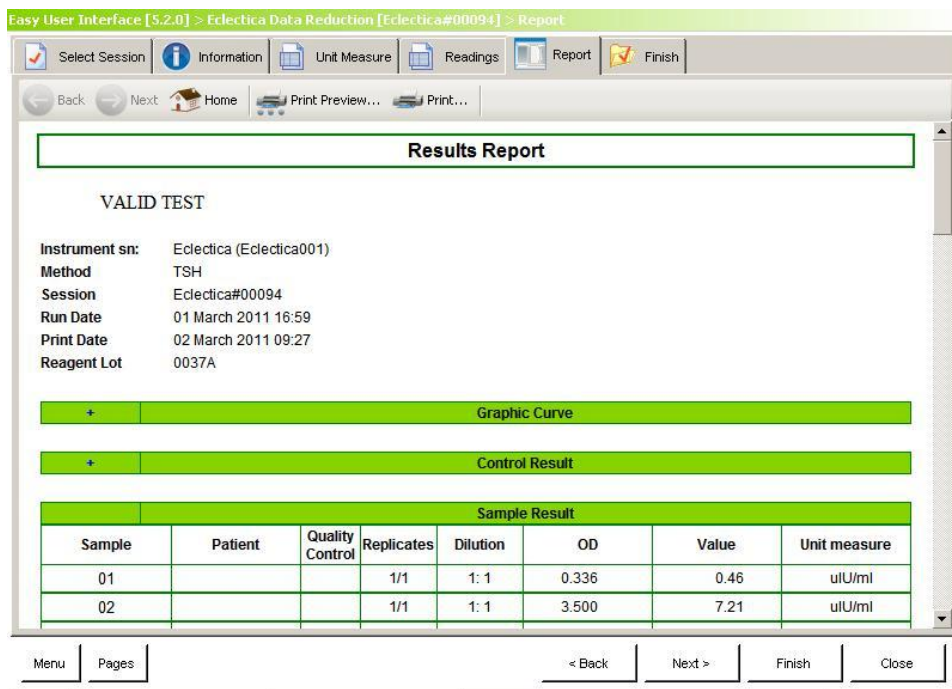


Fig. 7. 91

Clicking on the **Graphic Curve** symbol  reveals a graph of the Calibration Curve calculated with the 5-parameter interpolation method: (Fig. 7. 92)

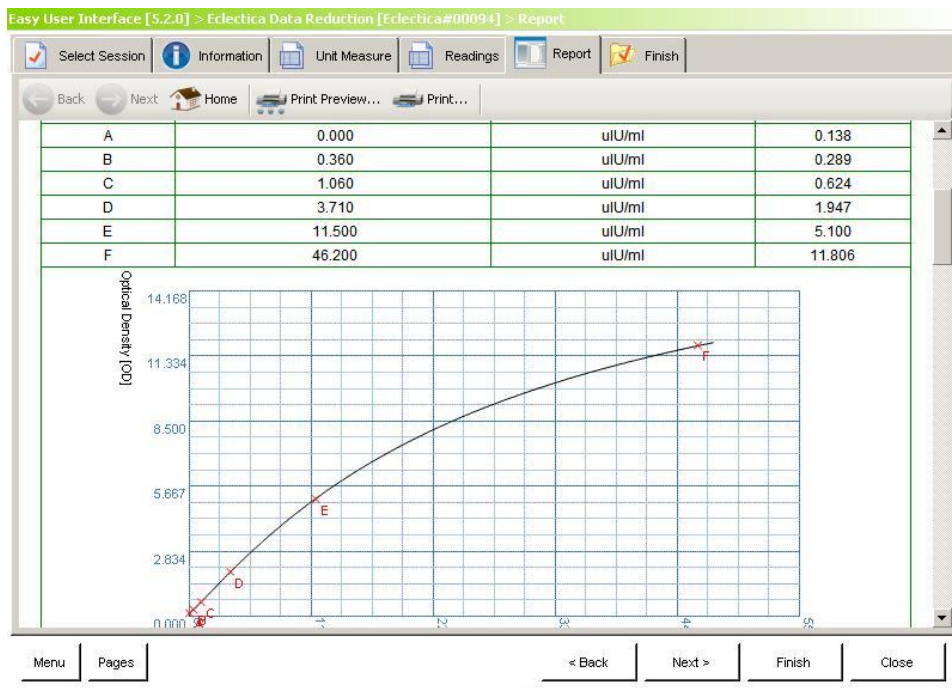


Fig. 7. 92

Click on the symbol  alongside **Control Result**, to display the values of controls and calibrators of the selected method (Fig. 7.94).

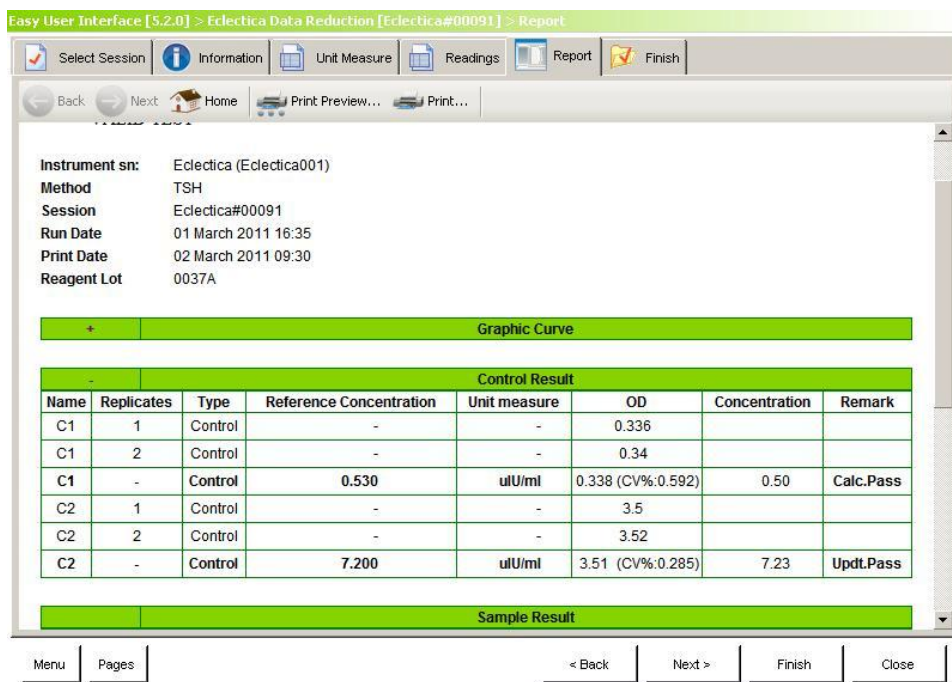


Fig. 7. 93

The lower area of the Report shows the reported values on the samples for the selected test:

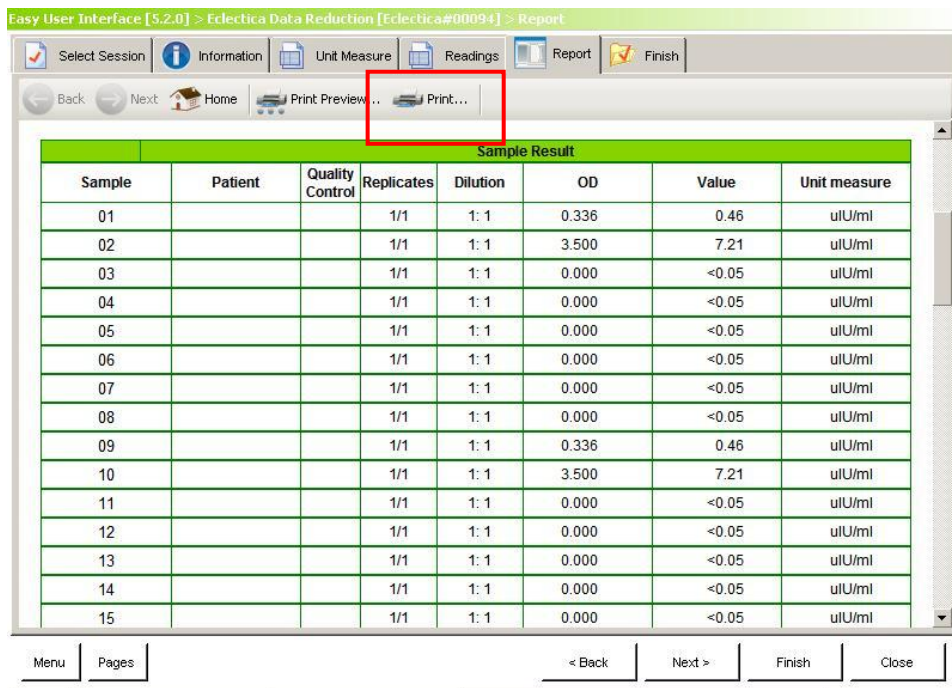


Fig. 7. 94

Press **Print** (Fig. 7.94) to print the report

Status of the test

The test status may be different according to the status of the calibration. The different conditions are listed below:

1. **Valid test:** it means either that the curve for that specific test is still valid or that the controls (or the curve, in case of 6-points calibration) have been accepted during the current run
2. **Temporary result:** The results are calculated using an expired calibration curve. The corresponding printout on the internal printer (during the run) shows these results in parentheses. The results can be confirmed within 24 hours.
3. **Test confirmed:** the calibration curve has been checked within 24 hours from the worklist execution and the controls were accepted. The software recalculates automatically the results according to the new calibration curve.
4. **Test not confirmed:** the calibration curve has not been checked within 24 hours.
5. **Invalid test:** the controls of a new kit lot number were not accepted, or the 6-points calibration curve has been rejected.

Report by Patient

Selecting the **Report by Sample** link in the Session Report page (Fig. 7. 91) the worklist report by patient is displayed.

The report gives the sample ID, list of tests executed, and the corresponding results and normal values for each patient.

Easy User Interface [5.2.0] > Eclectica Data Reduction [Eclectica#00091] > Report

Select Session Information Unit Measure Readings **Report** Finish

Back Next Home Print Preview... Print...

Report

Patient	20115001035026	Session	Eclectica#00091
Sample	SMP1	Run Date	01/03/2011
Name	John	Print Date	02/03/2011
Last Name	Smith	User	
Birth Date	05/03/1968	Instrument sn:	Eclectica
Sex	Male		

Method	Replicates	Dilution	Concentration	Unit measure	Expected Value
TSH	1	1:1	<0.05	uIU/ml	Healthy, 0.6 - 4.8 uIU/ml
HCG	1	1:500	<2500.00	mIU/ml	Male, < 1 mIU/ml Female <45 years old, <1 mIU/ml Female >45 years old, <5 mIU/ml Pregnant 4-8 weeks, 104 - 149000 mIU/ml Pregnant 9-12 weeks, 37700 - 225000 mIU/ml Pregnant 2nd Trimester, 5280 - 66600 mIU/ml Pregnant 3rd Trimester, 4280 - 87400 mIU/ml
HCG	1	1:100	<500.00	mIU/ml	Male, < 1 mIU/ml Female <45 years old, <1 mIU/ml Female >45 years old, <5 mIU/ml Pregnant 4-8 weeks, 104 - 149000 mIU/ml Pregnant 9-12 weeks, 37700 - 225000 mIU/ml Pregnant 2nd Trimester, 5280 - 66600 mIU/ml Pregnant 3rd Trimester, 4280 - 87400 mIU/ml

Menu Pages < Back Next > Finish Close

Fig. 7. 95

Shut Down Procedure

When the Work List/s have been executed, perform the Shut Down procedure as described in: "Shut Down" in Section 8: "Maintenance"



WARNING: If the Shut Down procedure is performed incorrectly this might compromise proper operation of the instrument.

QUALITY CONTROL

General Description

The ECLECTICA™ quality control program records the results of control serum assays in order to monitor the accuracy and precision of the ECLECTICA™ system.

The quality control procedure includes:

- definition of control serums to be used on the system.
- analysis of control serums together with patient samples.
- comparison of expected and actual results to evaluate the analytic performance of the system. This enables validation of the analysis and release of the report.
- Retrospective evaluation of the quality control results via statistical analysis of the results over time using graphic output.

Terminology

Quality control

A set of procedures aimed at validating a series of analyses by monitoring the accuracy and precision of the analytical system.

Mediana

The sum of all results divided by the number of results.

The mediana is calculated as follows:

$$\bar{x} = \sum_{i=1}^n x_i / n$$

Standard Deviation

Statistical parameter that describes the spread of a population of data around its mean value.

The standard deviation is calculated as follows:

$$SD = \sqrt{\sum_{i=1}^n \frac{(x_i - \bar{x})^2}{(n-1)}}$$

where n = number of results, and $\bar{x}$ = mean.

Coefficient of Variation (CV)

Statistical parameter that measures the spread of a population of analytical values around its mean.

The percentile CV is calculated as follows:

$$CV\% = (SD/Mean) \times 100.$$

Quality Control Directives

Quality control monitors the analytical quality of the system is an integral part of Good Laboratory Practice.

We explain below:

- How to select a control serum
- When to run quality control.

How to select a control serum

Always use control serums which are commutable with the patient serums on the ECLECTICA™ system. For this reason, use human origin control serums.

Adaltis recommends using control serums from the *Quality Street* range supplied by Adaltis itself and designed specifically for use with the ECLECTICA™ system.

When to run quality control

Use control serums on the ECLECTICA™ system every day for each level of each serum.

For further information on Quality Control Theory and operations, please see the “QCP.NET 4.2” software manual, supplied by Adaltis Srl on request.

Additional Functions

OpenLAB Options

The OpenLAB options can be accessed by selecting "Options..." on the Easy User Interface side bar (Fig. 7. 96) or pressing **Page->Options** and selecting the Options... item from the menu

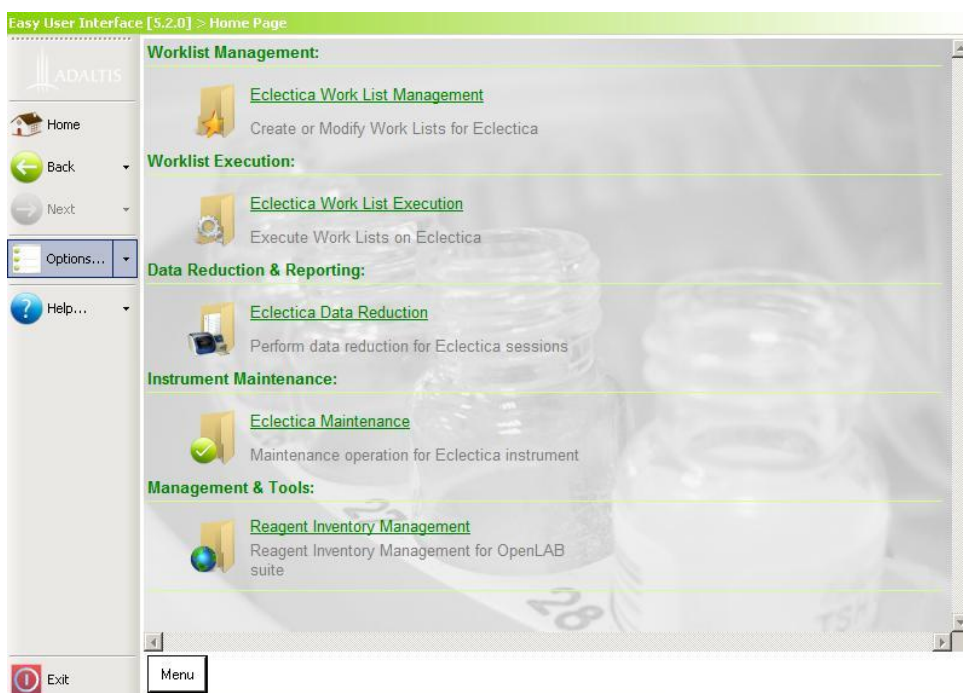


Fig. 7. 96

NOTE: It's strongly suggested to configure the options during the first installation of the instrument (some options cannot be configured by the user). Any further modification should be carried out with the help of an authorized Application Specialist. For more details about options configurations, please refer to Technical Bulletin ECL-0065_EN.

Reagent/Controls/Calibrator barcodes

If it is impossible to read the barcodes of the Specific Reagents, Controls and Calibrators from the labels, you can calculate them by following these rules.

The barcode is composed of 9 digits:

- 3 digits to identify the method
- 2 digits to identify the type of reagent
- 4 digits to identify the barcode key.

1) The 3 digits which identify the method are given in the following table.

Immunology Methods

ANALYTE / IMMUNOASSAY	Identifying no
IA 200 COMMON REAGENTS	099
DILUENTS for immunoassay	002
FSH	003
LH	004
HCG	005
PROLACTIN	006
ESTRADIOL	007
PROGESTERONE	008
TESTOSTERONE	009
DHEA-S	010
ANDROSTENEDIONE	011
SHBG	012
ALFA-PROTEIN (AFP)	016
FREE ESTRIOL	017
C-PEPTIDE	019
INSULIN	020
FERRITIN	021
CEA	023
FREE PSA	024
TOTAL PSA	025
OV - CA 125	026
GIC - CA 19-9	027
BR - CA 15-3	028
CORTISOL	029
ANTI-Htg	040
ANTI-TPO	041
FT3	043
FT4	044
T3	045
T4	046
TSH	047

Clinical Chemistry Methods

ANALYTE/ CLINICAL CHEMISTRY	ID no.
COMMON REAGENTS for CLINICAL CHEMISTRY	100
DIRECT BILIRUBIN	103
TOTAL BILIRUBIN	104
UREA U.V.	105
CHLORIDE	106
CHOLESTEROL	107
CHOLESTEROL -HDL	109
CREATININE	110
GLUCOSE	111
(AST) GOT	112
(ALT) GPT	113
LACTIC DEHYDROGENASE (LDH)	114
PHOSPHOROUS	115
TOTAL PROTEIN	116
TRIGLYCERIDES	117
URIC ACID	118
GGT	119
AMYLASE	120
CPK-NAC	121
CALCIUM	123
IRON	124
CK-MB	127
CHOLESTEROL LDL	135

2) The 2 digits that identify the type of Reagent, Control or Calibrator are shown in the following table.

Type of Reagent/Control/Calibrator

REAGENT TYPE / ECLECTICA	ID no.	Code Package
Calibrator A	40	04
Calibrator B	41	04
Calibrator C	42	04
Calibrator D	43	04
Calibrator E	44	04
Calibrator F	45	04
Calibrator G	46	04
Calibrator H	47	04
Reagent 1 for immunoassay	48	01
Reagent 2 for immunoassay	49	01
Control Serum 1	50	01
Control Serum 2	51	01
Substrate	52	02
Stop solution	53	02
Separation agent	55	02
Diluent 1	56	03
Diluent 2	57	03
Diluent 3	58	03
Diluent 4	59	03
Diluent 5	60	03
Multicalibrator for Clinical Chemistry	64	07
Reagent 1 for Clinical Chemistry	65	06
Reagent 2 for Clinical Chemistry	66	06
Calibrator for Immunoassay (Calibration Set)	67	04

3) The 4 digits that identify the barcode key are given in the BarCode field in the Reagents Kit page (for Specific Reagents and Controls) and the Calibration Kit page (for Calibrators) in the Reagents Management module.

Clinical chemistry multicalibrators Barcode keys

MULTICALIBRATOR	ID no.	Analyte
Multiparametric Calibrator for Clinical Chemistry	601	ACP, ALP, ALT-GPT, AMYLASE, AST-GOT, BIL-DIR, BIL-TOT, CA, HDL, CK-NAK, CREAT, CHLORIDE, GGT, GLUCOSE, IRON, LDH-P, MAGN, PHOS, PROTEIN, TRIGLYC, UREA, URIC ACID.
Calibrator for HDL Cholesterol	602	HDL Cholesterol
Calibrator for LDL Cholesterol	603	LDL Cholesterol

SECTION 8

MAINTENANCE

General Rules

Proper maintenance of the ECLECTICA™ system is one of the activities of foremost importance in order to guarantee that:

- the system is kept in ideal operating conditions so that correct results are guaranteed;
- all checks, adjustments and repairs are scheduled in advance, before the analytical results are compromised;
- loss of time due to system Shut Down is minimized.

This Section provides the user with general recommendations for proper maintenance of the instrument.

Maintenance comprises operations that must be performed by the user daily, weekly and whenever the need arises.

Also periodic maintenance activities are envisaged (usually every six months), to be carried out by qualified Adaltis Srl Technical Service personnel.



WARNING: Improper maintenance could jeopardize good operation of the system.

The daily and weekly maintenance procedures described in this Section must be performed by the user who works with the analyzer.

Should the system's parts fail or break, any repair or replacement must be carried out by technical personnel authorised by Adaltis Srl.

The user must make sure that:

- **the ECLECTICA™ work area is always clean;** continuous instrument inspection is a decisive factor in assuring good operation of the system; any leaks of liquids in the work area are rinsed immediately with distilled water and then dried;
- all waste materials are disposed of in observance of local safety regulations and laws;
- **The information on infected liquids** given in this manual is followed carefully (see Section 1 **"Safety "** and Section 2 **"Labelling"**).

Maintenance procedures

The following procedures are described hereunder:

- Instrument Start Up and Shut Down.
- Wash cycles.
- Replacement of the consumable materials (Common Reagents, Reaction Segments, Thermal Paper),
- Disinfection.



WARNING: All maintenance procedures must be implemented in observance of the safety precautions given in Section 1 of this Manual.

The following maintenance procedures must be done, depending on the activity in question, at the following periods:

- daily,
- weekly,
- whenever necessary.

To be effective, the maintenance procedures must be run scrupulously at their scheduled times.

From the Main Menu, select the *Eclectica Maintenance System* icon (Fig. 8.1) to enter the section reserved for instrument maintenance.

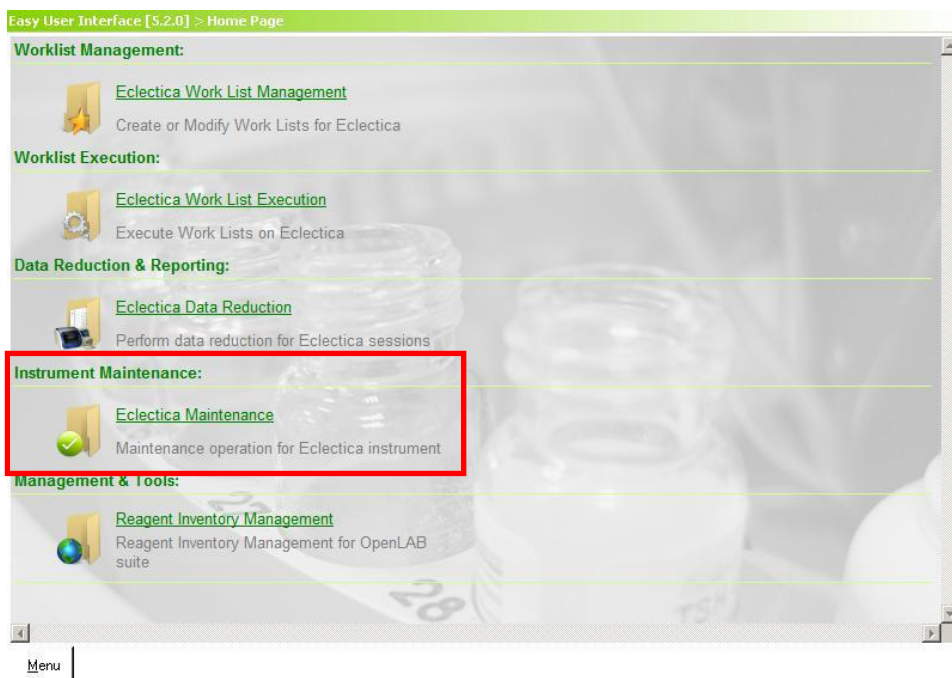


Fig. 8. 1

The OpenLAB software Maintenance Section allows the following procedures to be performed:

- Daily instrument maintenance
- Weekly instrument maintenance
- Loading Common Reagents
- Changing Reaction Sectors
- Checking Blanks
- Autozero

Daily Maintenance

Startup

The **Daily Start up** procedure must be carried out at the start of each work session when the analyzer has been idle for less than **48 hours since the end of the last session**.

Once the type of Start Up has been selected, the ECLECTICA™ analyzer will automatically perform the lines pre-flushing and check procedures:

- AUTOZERO (filters and spectrophotometer check)
- IA blanks check

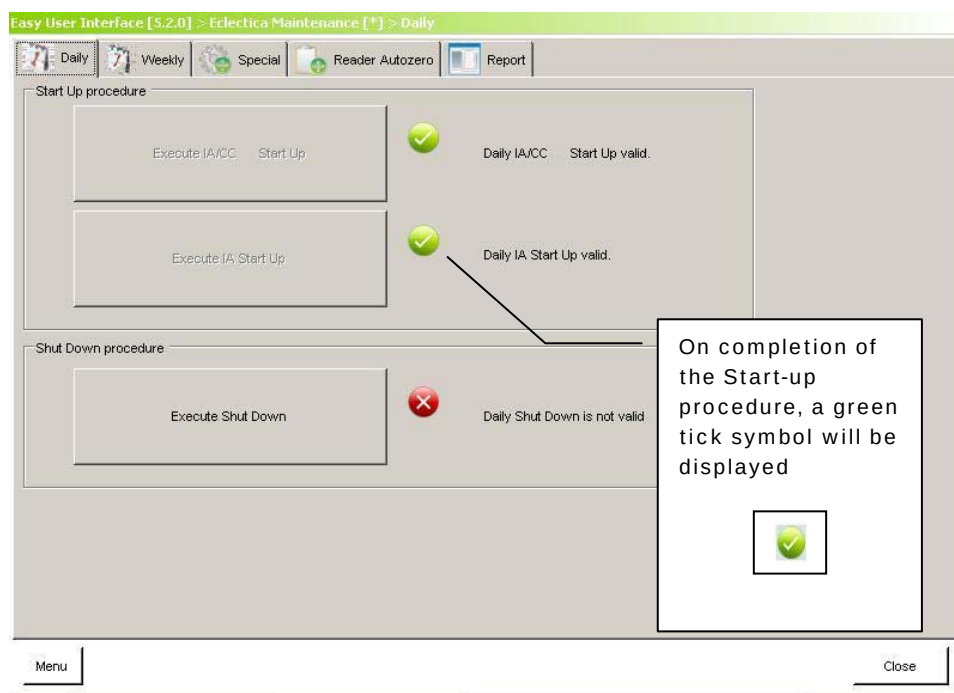


Fig. 8.2

It is possible to perform a complete start-up procedure or a limited procedure for Immunoassay tests.

On completion of the start-up procedure, the execution end message will be displayed (Fig. 8. 3) indicating whether or not the instrument is ready for tests.

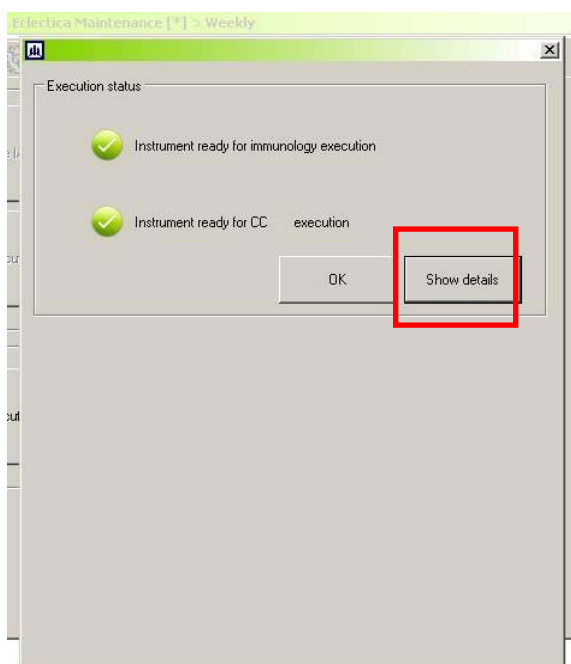


Fig. 8.3

Press *Show Details* (Fig. 8.4) for further details on the result of the Start Up procedure executed on the analyzer:

- Blanks
- Check of operation on the filters utilised.
- IA Start up Procedure Result
- CC Start Up Procedure Result



Fig. 8.4



WARNING if the instrument is switched off after the Start Up, the entire procedure must be repeated

Shut Down, to be run whenever the analyzer is to be switched off (see: "*Shut Down*").

NOTE: if the analyzer is not used for more than 48 hours, the software will prompt the user to perform a washing procedure with the Cleaning Kit (see: "*Wash with Cleaning Kit*") before running the Shut Down procedure.

Emptying the Waste Discharge Tank, (see: "*Emptying the Waste Discharge Tank*"). The Waste Tank must be emptied at the end of each work session.

At the end of each working day:

- remove all of the sample test tubes from the Samples Carousel,
- remove the container of Separation Agent from the Samples Carousel, close it and store it in a refrigerator at 2-8 °C,
- check that there are no leaks of liquid or spills in the work area; if necessary, clean as instructed in: "*Disinfecting the work area*".

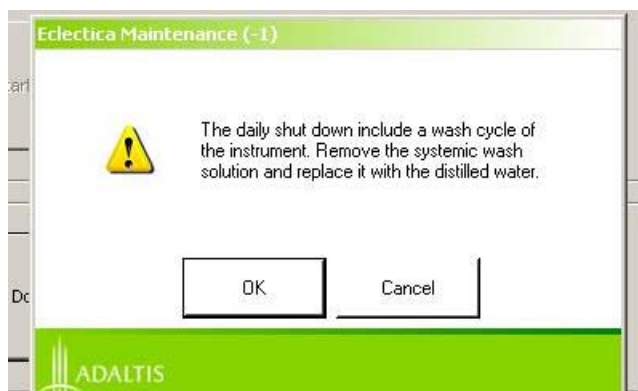
For storing Reagents, see: "Storing consumables on board the instrument"

Shutdown

From the **Daily** page press the **Execute Shut down**



This displays the message

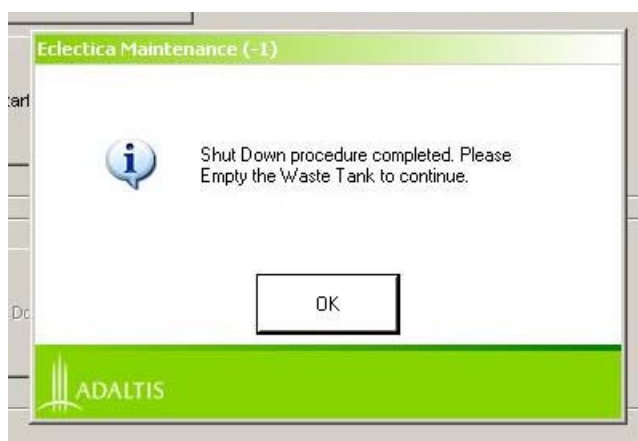


Follow the instructions and click on **OK**: the analyzer automatically performs a wash cycle of:

- sampling needles,
- reaction cuvettes wash needles,
- flow cells and reading system needles.

using distilled water.

On termination, the following message appears



Click on **OK**.

Empty out the Waste Discharge Tank.

Another message appears:



click on **OK**.



WARNING: Quit the Windows operating system before switching the instrument off.

You can now set the power switch to **OFF**

The refrigeration system switch can be left **ON** if required.

Weekly Maintenance

Startup

To ensure correct charging of the lines, run a **weekly Start Up** in the following circumstances:

- the analyzer has not been used for more than 48 hours,
- the common reagents are replaced,
- wash cycles are executed,
- the analyzer has just been installed.

Run the following procedures with reference to the appropriate Sections of this manual:

- External cleaning of sampling needles.
- Cleaning the barcode reader.
- Cleaning the work area.
- Wash with Cleaning Kit.

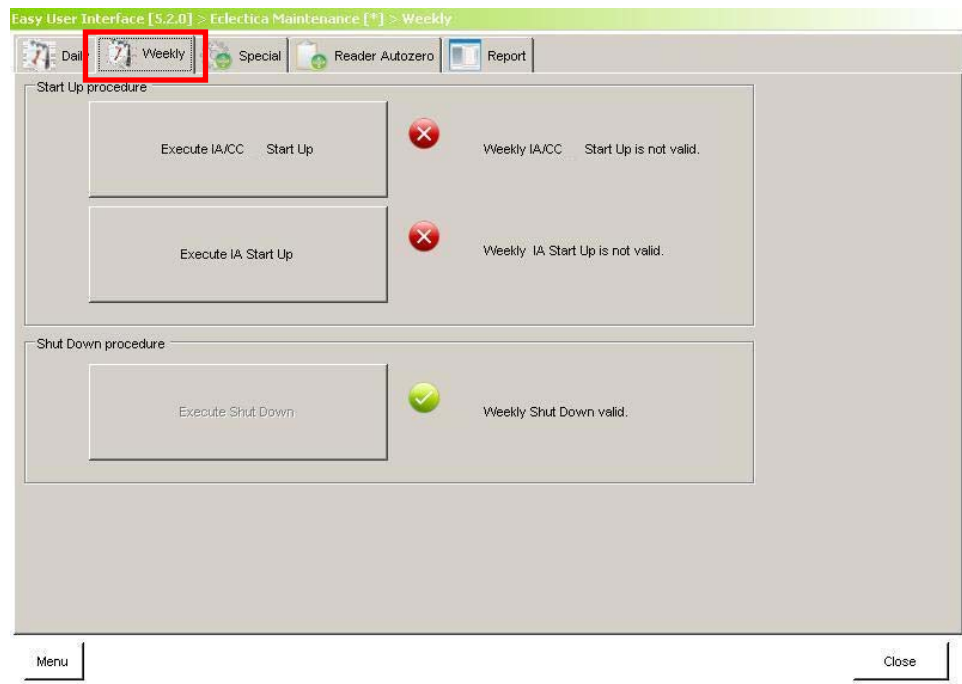


Fig. 8.5

Select the **Weekly** tab and perform the operations as described in "Daily maintenance"

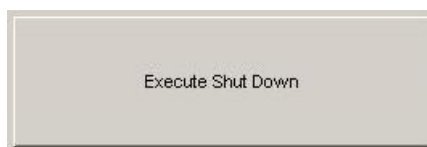
Shutdown

The weekly shutdown includes a washing with the cleaning kit (code: 1700006). This kit is composed by:

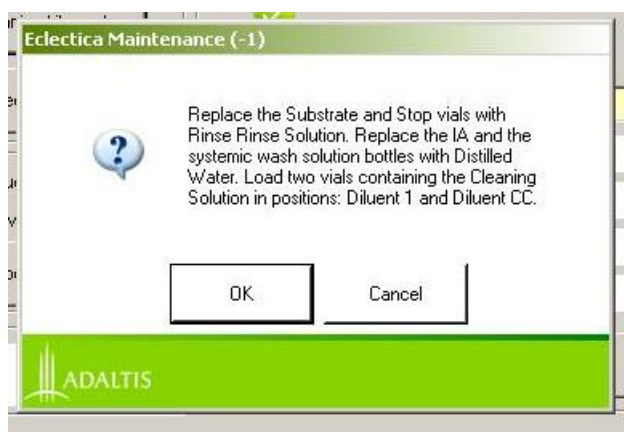
- 2 bottles of rinse solution: they are used to clean substrate and stop solution tubings
- 10 bottles of cleaning solution: they are used to clean the dispensing needles, the washing head, the flow cells aspiration needles and the flow cells themselves.

For the procedure see below.

From the **Weekly** page press the **Execute Shut down**



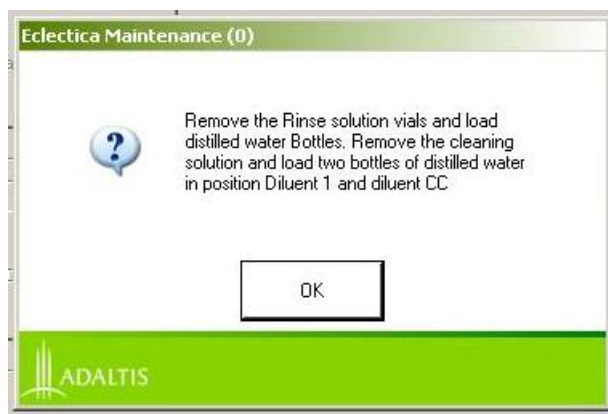
This displays the messages



Replace the liquids as per instrument's instructions and then click **Ok**: the instrument will automatically perform the washing with cleaning kit procedure (see "*Washing with cleaning kit*" in this Section); the wash cycle will clean:

- sampling needles,
- reaction cuvettes wash needles,
- flow cells and reading system needles.

After the first part of the procedure has been completed, the following message will appear:



Replace the liquids as above and click on **OK**.
On termination, the following messages appear



Click on **OK** in both cases.

Empty out the Waste Discharge Tank.



WARNING: Quit the Windows operating system before switching the instrument off.

You can now set the power switch to **OFF**

The refrigeration system switch can be left **ON** if required.

Special

The **Special** page (Fig. 8. 6) is used to perform the following maintenance procedures:

- Cleaning the instrument
- Emptying the Waste Discharge Tank.
- Loading Common Reagents
- Cleaning Kit
- Washing Needles
- Replacement of Sectors
- Blank Check (IA)

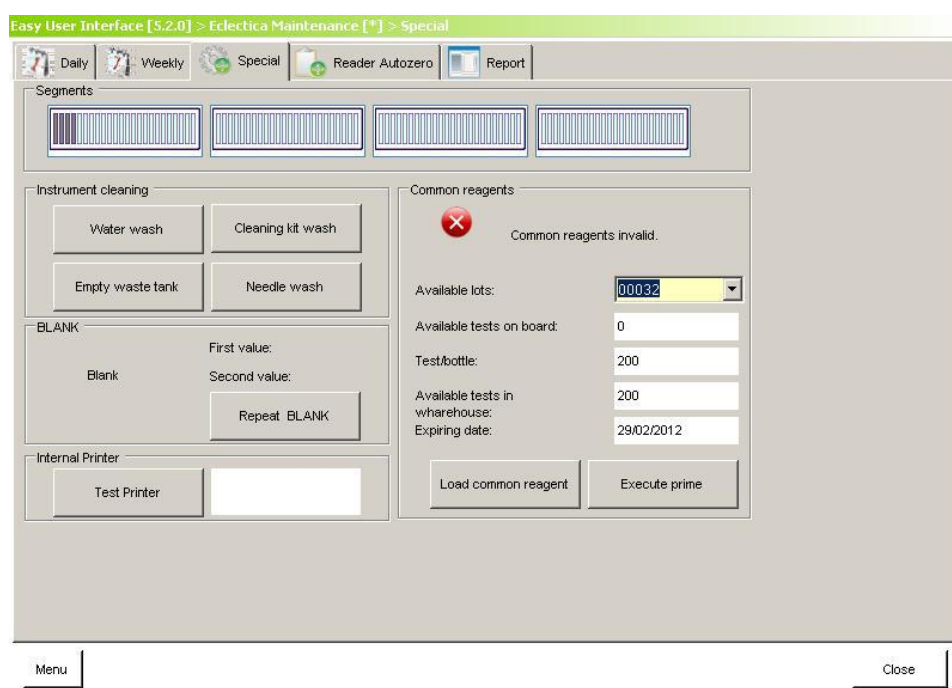


Fig. 8. 6

Wash with distilled water

From the **Special** page (Fig. 8. 6) press **Water Wash**.

This opens a confirm dialogue box (Fig. 8. 7).

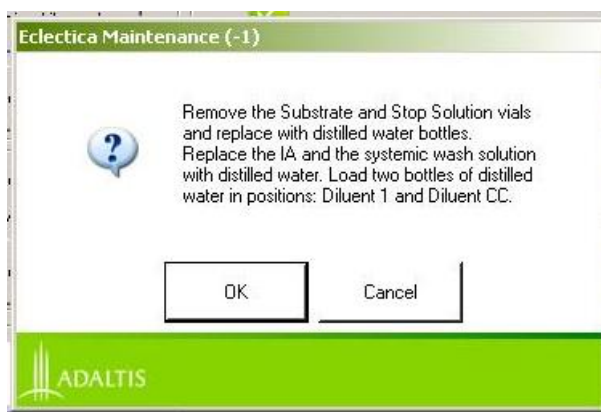


Fig. 8. 7

- Open the drawer on the right side of the instrument,
- Unscrew the caps of the connection systems of the vials of Substrate, Stop Solution and Immunoassay Wash Solution and Clinical Chemistry Wash Solution,
- replace them with vials of distilled water. Load two vials containing distilled water in the CC diluent 1 and diluent positions (Fig. 8.8)

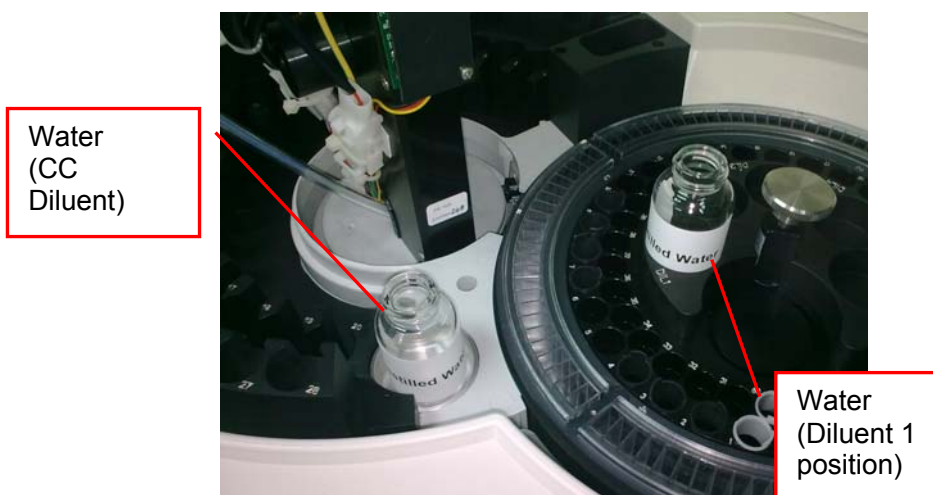


Fig. 8. 8

NOTE: Close the Common Reagents vials disconnected from the analyzer and store them as indicated on their labels.

Click on **OK** to start the Distilled Water wash.

On completion, the message ***Cleaning Procedure Concluded*** is displayed, click on **OK**.

Wash with Cleaning Kit

NOTE: The Cleaning Kit is supplied by Adaltis Srl. Do not use any other product for this purpose.

From the **Special** page (Fig. 8. 6) press ***Cleaning Kit wash***.

This opens a confirm dialogue box: (Fig. 8. 9)

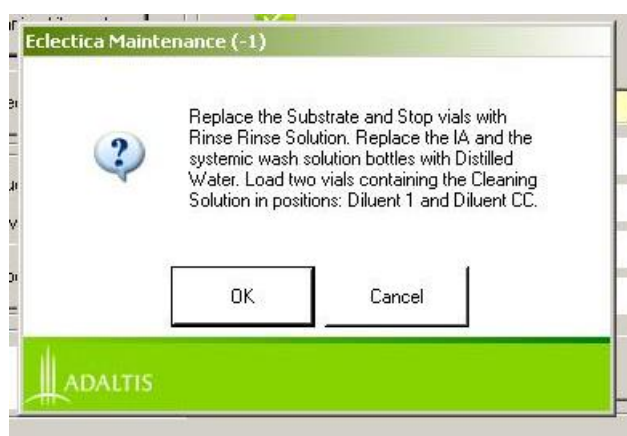
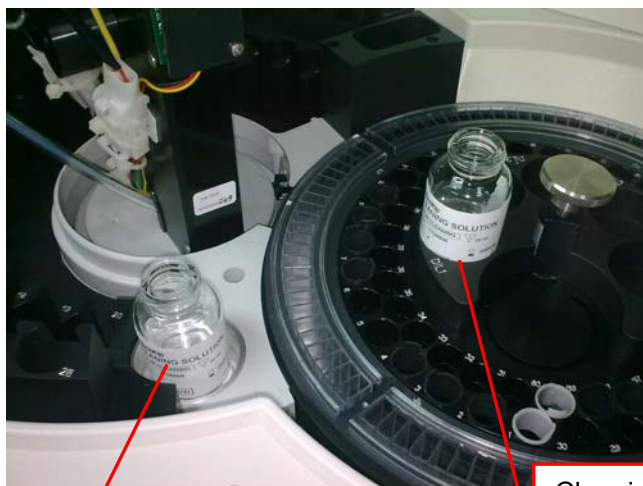


Fig. 8. 9

- Open the drawer on the right side of the instrument.
- Undo the Substrate and Stop vial caps.
- Replace the vials with vials of Rinse Solution.
- Undo the connection caps on the Immunoassay wash and Clinical Chemistry wash solution bottles and replace them with cleaning solution bottles (distilled water).
- Load two bottles containing the cleaning solution in the diluent 1 and CC diluent positions (Fig. 8. 10)



Cleaning solution
(CC Diluent Position)

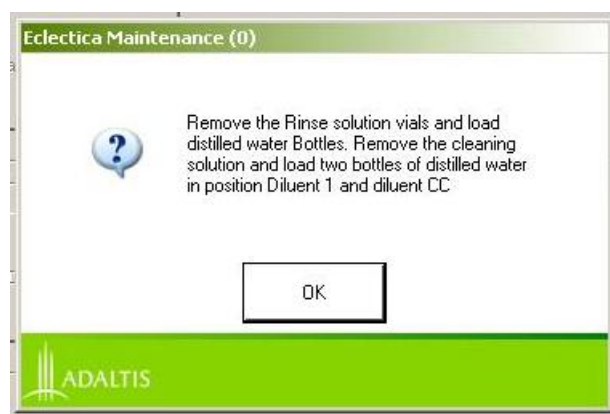
Fig. 8. 10

Cleaning
solution (Diluent
1 position)

NOTE: Close the Common Reagents vials after disconnecting them from the analyzer and store as indicated on their label.

Press **OK** to start the Cleaning Kit wash procedure.

On completion, the following message appears:



Replace the vials and press **OK**.

Sampling Needles Wash



WARNING You should perform this wash procedure if the analyzer returns imprecise results.

From the **Special** page (Fig. 8. 6) **Special** press **Wash Sampling Needles**.

This opens a confirm dialogue box: (Fig. 8. 11).

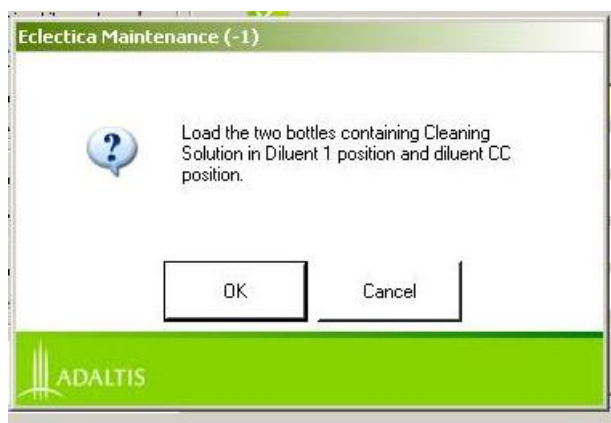


Fig. 8. 11

Load the two vials containing the cleaning solution in the diluent 1 and CC diluent positions.

Click on **OK** to start the wash with cleaning solution.

On completion, the following message appears: ***Remove the Cleaning Solution vials and install the Distilled Water vials.***

Press **OK**. Now run a Distilled Water wash.

Emptying the Waste Discharge Tank

NOTE: Empty the Waste Tank at the end of every working day. If the waste tank fills up during a session, the session will terminate.

The waste tank has a capacity of around 1700 ml. When the Waste Tank needs emptying, the User is notified by a message.

From the **Special** page (Fig. 8. 6) **Special** press **Empty Waste Tank**.

This opens a confirm dialogue box:

Have you emptied the Waste Tank? (Fig. 8. 12).



Fig. 8. 12

Empty the Waste Tank and press **OK**.

Replacing and Loading Common Reagents

Replace the Common Reagents as follows:

- Keep Common Reagents (Substrate, Stop, Separation Agent) at room temperature for **30 minutes** before installing them on the analyzer,

NOTE: All Common Reagents (Substrate, Stop, Separation Agent) must be replaced at the same time.

- Open the door on the right side of the instrument, unscrew the probe caps on the individual vials and remove the vials from the reagents drawer,
- The Separation Agent must be removed from the centre of the Samples Carousel,
- run a Cleaning Kit wash (see *"Wash with Cleaning Kit"*),
- install the new bottles of Substrate and Stop and the container of Separation Agent.

To install Common Reagents, see:

- ***Section 3: Installation, "Connecting the Waste Tank/Accessory Vials"***
- ***Section 7: "Loading Common Reagents" operating procedure.***

Select the lot from the Available lots menu (Fig. 8.6)



WARNING A message confirms the presence in the warehouse of at least one kit of common reagents of the selected lot.



WARNING A message prompts the user to perform a wash with cleaning kit before changing the common reagent vials.

From the **Special** page (Fig. 8. 6)

Press **Load common reagent**.

This opens a confirm dialogue box:

All tests that can still be executed will be lost. Continue?

(Fig. 8. 13).

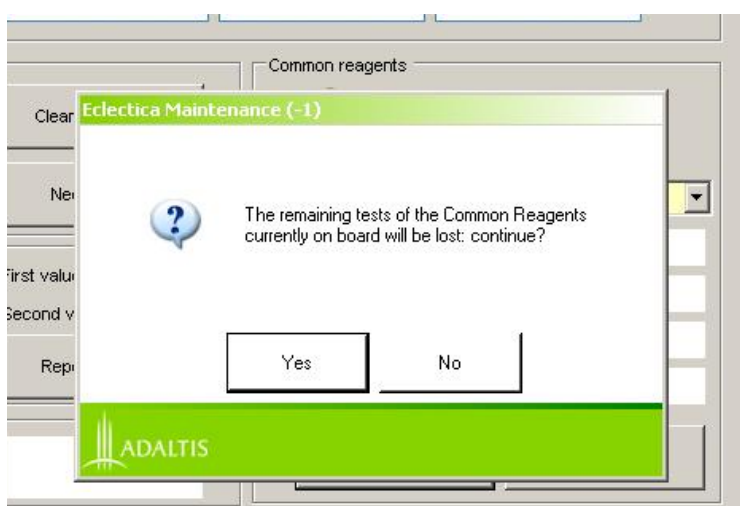


Fig. 8. 13

Click on **Yes**: the number of tests (200) of the new package of Common Reagents will be made available.

The analyzer will automatically charge the Substrate and Stop Solution lines.

On completion of the charging procedure, a message will be displayed confirming that the Common Reagent vials have been loaded.

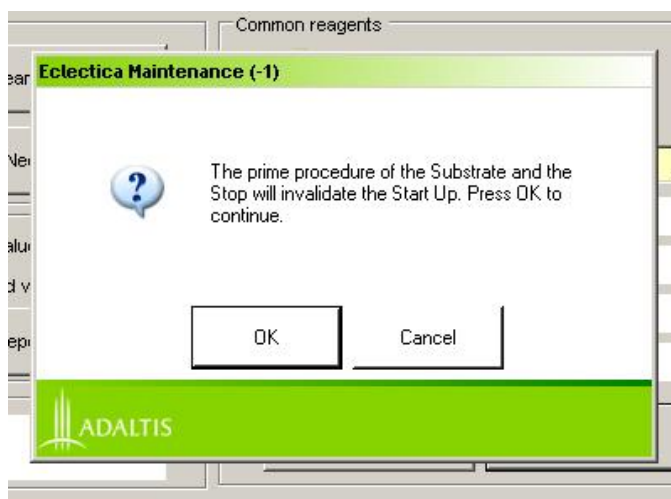
NOTE: After replacing the Common Reagents, before starting a new session, run the weekly Start Up procedure.

Click on **No** to abort the procedure.

Filling the Hydraulic Circuits

From the **Special** page (Fig. 8. 6) press **Execute Prime** (Fig. 8.16) to fill the hydraulic circuits.

A window will open containing the following message



Press OK to start the filling procedure. Subsequently it will be necessary to launch the start-up procedure (see *Daily Maintenance* and *Weekly Maintenance* in this section)

Replacement of Reaction Sectors

From the **Special** page (Fig. 8. 6) select the sector **(1-4)** corresponding to the sector to replace (Fig. 8.14).

After selecting the sector the Samples Carousel rotates to make the sector in which the selected segment is to be installed available to the user.

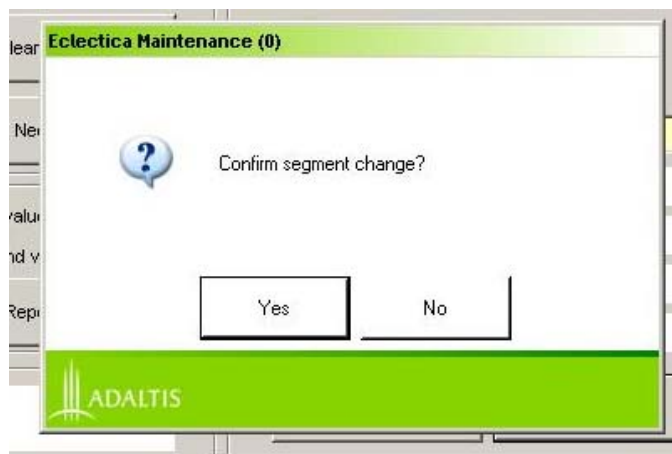


Fig. 8.14

Press **Yes** to confirm. Fit the Reaction Segments into the relevant wells as shown in (Fig. 8.15).



Fig. 8.15

Checking Blanks

If the values of Blanks 1 and 2 fall outside the required limits: between -1 and 150 mOD, repeat the Blanks execution procedure for the immunoassay test.

From the **Special** page (Fig. 8. 6) press **Repeat BLANK** (Fig. 8. 7).

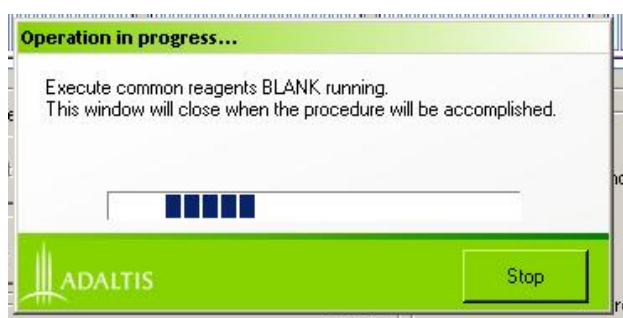
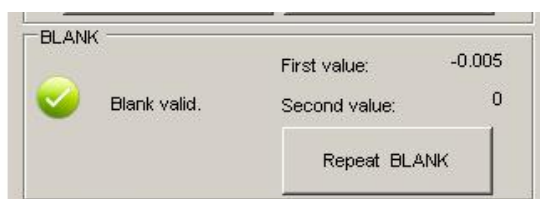


Fig. 8.16

Once the blanks have been checked, the values of blanks 1 and 2 on the two cuvettes will be displayed



If the error message reappears, change the Common Reagents vials after an adequate washing procedure (see "Replacing Common Reagents" in Section 8: Maintenance)

If the values obtained for Blanks are still outside the limits, only Clinical Chemistry tests can be executed.

Autozero

To ensure correct spectrophotometer readings, the ECLECTICA™ analyzer performs a reading test to check operation of the filters.

The procedure resets the photometer using the wash solution (the readings are expressed in 1/10 mV).

From the *Reader Calibration* page (Fig. 8.17) the following procedures can be executed:

- Autozero for Immunoassay & Clinical Chemistry tests
- Autozero for Immunoassay only
- Autozero for Clinical Chemistry tests only

Press **Execute only IA** to perform the zero procedure for Immunoassay tests only (Fig. 8.17).

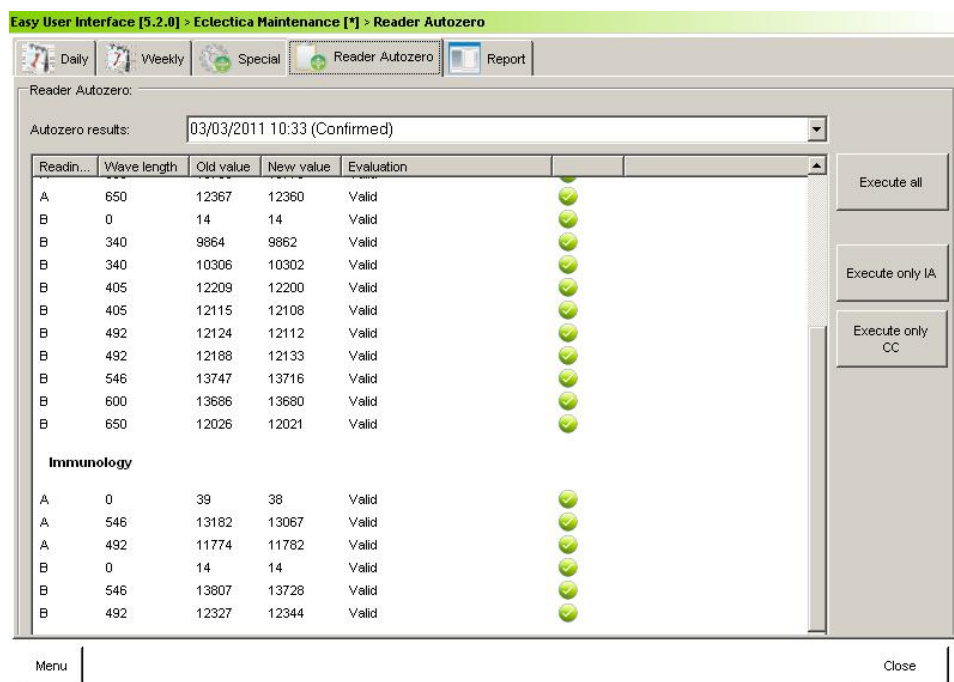


Fig. 8.17

This displays the message: **"Are you sure to execute the calibration for immunology filters?"**. Select **Yes**: the instrument will perform the photometer autozero procedure.

On termination of this procedure, if the values obtained are higher than 8,500, a green tick symbol will be displayed  alongside the reading values of the reference filters, and a message will indicate that the analyzer is ready for operation (

Fig. 8.17). The values of the Clinical Chemistry methods are displayed at the top of the window, the Immunoassay ones at the bottom.

If the values are lower than 8,500, a yellow tick symbol will be displayed  alongside the reading values of the reference filters. The system is ready for operation, but it is advisable to contact the Adaltis Hotline Service since the photometer lamp may be at the end of its service life.

If the values are between 7,500 and 8,500 the system is ready to operate, but we recommend contacting the Adaltis Hot-Line Service because the photometer lamp may be approaching the end of its service life.

If the values are lower than 7,500, a red tick symbol will be displayed  alongside the reading values of the reference filters. the filter is not operational and the ECLECTICA™ instrument cannot run the tests in question.

Contact the Adaltis Hotline Service.

Cleaning

External cleaning of the barcode reader

Use a gauze or cotton cloth dampened with distilled water to clean the barcode reader's scan window.

Dry off, making sure there are no deposits or blemishes on the window.

External cleaning of needles and work area

Follow the procedure given in *"Disinfecting the Work Area and Disinfecting Metal Needles"*.

Storing consumables on board the instrument

Clinical Chemistry Reagents, Controls, Calibrators and Diluent:

The vials may be left on the instrument in compliance with the user instructions for each analyte; make sure the Refrigeration System is left in operation and that the vials are closed with their respective caps. Otherwise, at the end of the work session, remove all vials, close them with their caps and store them in a refrigerator at 2-8 °C.

Common Reagents:

The vials can be left on board the analyzer for a maximum of two weeks.

Common Reagents (Separation Agent), IA Diluents and CC Multicalibrator:

The container of Separation Agent, the Diluents, and the Multicalibrator must be removed at the end of the day, closed with their caps and stored in a refrigerator at 2-8°C.

Changing the Thermal Paper

Periodically check the amount of thermal paper on the analyzer.

A red line appears on the paper to show that the roll is almost empty.

If necessary, replace the paper as follows.

- Press the white button on the right side of the printer door. The blue lever on the right side of the printer lifts to indicate that the lock mechanism has been disabled.
- Open the door, remove the old roll and replace it with a new one.
- Insert the paper in the guide and lower the blue lever so the paper advances.
- Close the door.

NOTE: If the paper runs out while a WorkList is running, the *Start* page will display the message *Printer out of paper*.

In this case the results of the assays will not be automatically printed out on the internal printer.

However, all results from a session can be printed by clicking on Results in the Start page before closing it.

Disinfection

The essential information for disinfecting the instrument properly is given below.



WARNING read Section 1 - "Safety" carefully before servicing the analyzer.

Certain maintenance activities should be carried out only when wearing coveralls with long sleeves having elastic band cuffs, hard-wearing rubber gloves and protective goggles.

Disinfecting operations must be performed using two sodium hypochlorite solutions (commercial hypochlorite) at concentrations of **1% and 0.5%**.

Commercial hypochlorite usually has a 5.25% concentration; in this case, prepare the solutions as follows:

- Solution A (approx. 1%): 200 ml of hypochlorite and 800 ml of deionised water.
- Solution B (approx. 0.5%): 100 ml of hypochlorite and 900 ml of deionised water.



WARNING: The treatment recommended in this Section does not ensure that the instrument becomes sterile, i.e. that all of the viruses and microorganisms are completely inactive, but it minimises the risk of contamination



WARNING: Before using any disinfecting method other than the one recommended by the manufacturer, the user must check with the manufacturer that the proposed methods will not damage the instrument



WARNING: Make sure the analyzer has been switched off (main switch OFF, "O" symbol) and the power cable has been disconnected.

Disinfecting the Work Area

- Dampen all surfaces showing traces of deposits of contaminating liquids with cotton wool soaked in Solution A.
- Remove the deposits.
- Dampen all other surfaces with the same Solution. A film of moisture should remain on the surfaces for at least 15 minutes in order to achieve an acceptable level of disinfection.
- Remove the hypochlorite with cotton wool soaked in deionised water.

Disinfecting the metallic needles

- Clean all metal needles carefully (reagent/sample dispensing needles and wash solution dispensing needles) with cotton wool soaked in Solution A.
- Remove the hypochlorite with cotton wool soaked in deionised water.

Disinfecting the waste tank

- Completely empty the Waste Discharge Tank.
- Fill the tank with Solution B and leave for approximately one hour,
- Thoroughly rinse with deionised water.

NOTE: The treatment described above does not ensure that the instrument becomes sterile, i.e. that all of the viruses and microorganisms are completely inactive, but it minimises the risk of contamination.

The table shows the maintenance procedures and frequencies.

Procedure	Details	Every day	Every week	Whenever necessary
Daily Start Up	Charge Common Reagent lines, run autozero.	✓		
Weekly Start Up	Charge Common Reagent lines, run autozero.		✓ At the beginning of the working week or if the instrument has not been used for more than 24 hours.	After a new package of Common Reagents is installed.
Shut Down	Wash: sampling needles, reaction Cell washing needles, reading system needles, flow Cells.	✓		
Wash with Cleaning Kit	Wash Common Reagent lines with Rinse Solution and Distilled water/Wash sampling needles with cleaning solution		✓	✓ At each change of Common Reagent bottles.
Wash with Distilled Water	Wash Common Reagent lines/sampling needles with Distilled Water			✓
Empty the Waste Discharge Tank	Empty the fluids contained in the Waste Discharge Tank	✓		✓
Clean the exterior of the sampling needles, barcode reader, work area.	Clean with gauze or cotton cloth dampened with hypochlorite solution		✓	
Washing the Sampling Needles	Wash the sampling needles with cleaning solution			✓

SECTION 9

TROUBLESHOOTING

This Section describes the errors/malfunctions which may arise during operation of ECLECTICA™ and the corrective actions required to remedy them.

It covers both problems that may foreseeably arise during operation of the analyzer and unexpected software error messages: These error messages are normally in English since they are generated by the Operating System (Windows XP) or the application development environment.

The error messages/malfunctions fall into the following categories:

- **Generic error/malfunction messages**
- **Start Up error/malfunction messages**
- **Smart Card error/malfunction messages**
- **Barcode reader error/malfunction messages**
- **Execution and report error/malfunction messages**
- **Invalid test results.**

Generic error/malfunction messages

1. The instrument fails to switch on

Error	Probable cause	Solution
The display is blank	Mains power loss.	- Check that the power cable is connected. - Check that both switches on the back of the instrument are ON.

2. The PC does not turn on

Error	Probable cause	Solution
Message displayed: <i>None System Disk or disk error</i>	The HDD could be damaged.	Inform the Adaltis Hotline Service
White text on blue background	Problem with the operating system or hardware	Switch off the computer and switch it on again after a few seconds.
The <i>Eclectica</i> application fails to start. Message displayed: <i>PV error or Access Violation</i>	The software fails to connect to the instrument	Inform the Adaltis Hotline Service.

3. Generic runtime errors

Error	Probable cause	Solution
The software does not respond to commands	The software has generated an unexpected error.	Press CTRL-ALT-DEL on the keyboard. Now select Task Manager and then the Applications tab. Select Eclectica and then End Task. Close Task Manager with the X button at the top left of the window. Restart Eclectica (click on the Eclectica icon on the desktop and press Enter).
Message displayed: <i>Key Violation</i>	An invalid action has been performed.	Restart Eclectica as per the above instructions
The following errors appear: <i>XV/RV/RV1/MY/WQ /VT/OT</i>	Software/instrument communications error.	Press OK: if the software still does not work properly, restart it as per the above instructions. If the application does not respond and a current worklist cannot be completed, proceed as indicated in the previous point.
Internal printer does not print	- No paper in the printer. - The paper is incorrectly loaded	Load the paper and try again. The blue paper lock lever is not engaged (down).
External printer does not print	The printer is not switched on or not on-line.	Check that the printer is switched on and, if the printer has the option, select On Line operation.

Start Up error messages

1. Generic Start Up errors

Error	Probable cause	Solution
IA (or IA/CC) daily/weekly Startup not valid (all the autozero values or only IA or only CC show a red dot with white cross)	- The segment has not been placed in position 1. - Possible bubble in the reading Cell. - The reading Cells may be broken. - Empty hydraulic circuit - Normal lamp deterioration.	Check that the Reaction Segment is in position 1 and that the first 4 reaction Cells are clean. If OK, repeat the Autozero procedure. If the problem persists, contact the Adaltis Hotline
IA Blank not valid	- An out of range absorbance has been measured - The values of Blanks 1 and 2 are out of the range from -1 to 150 mOD	Selecting " Repeat Blank " (Section 8: Blanks Check) only Clinical Chemistry tests can be performed. Selecting " Repeat Blank " (Section 8: Blanks Check), ECLECTICA™ will repeat the blanks execution procedure. If the error message reappears, change the Common Reagents vials after an adequate washing procedure (see " Replacing Common Reagents " in Section 8: Maintenance)
All the filters are out of range	- The segment has not been placed in position 1. - Possible bubble in the reading Cell. - The reading Cells may be broken. - Empty hydraulic circuit - Normal lamp deterioration.	Check that the Reaction Segment is in position 1 and that the first 4 reaction Cells are clean. If OK, rerun the Autozero. If the problem persists, contact the Adaltis Hotline
Photometer cells temperature error	The photometer cells have not reached the preset temperatures	Repeat the Start up procedure. If the problem persists, contact the Adaltis Hotline
Startup not valid	- IA autozero error (only for IA Start Up) - Error on Common Reagent Blanks (only for Immunology Start Up) - Error on CC and IA autozero (only for IA + CC Start Up)	Repeat the Start up procedure. If the problem persists, contact the Adaltis Hotline

Smart Card error/malfunction messages

Error	Probable cause	Solution
Message displayed: <i>ERROR B06: READ CARD ERROR</i>	- the Smart Card was not inserted correctly - the Smart Card was removed from the reader too soon. - the Smart Card is defective and cannot be read by the Smart Card reader	- Insert the Smart Card correctly - Replace the Smart Card. - Call the Adaltis Hotline Service.
Message displayed: <i>ERROR B02: CARD NOT VALID (ALREADY USED)</i>	The card has already been read	Use a new Smart Card.
Message displayed: <i>error in Smart Card driver (A02)</i>	There is a problem with the Smart Card reader driver	Inform the Adaltis Hotline Service

Barcode reader error/malfunction messages

Error	Probable cause	Solution
The barcode reader does not read the vial barcode or reads it only partially	- The barcode reader lens may be dirty. - The vial labels may be damaged.	Clean the barcode reader lens with a soft cloth and distilled water. Repeat the scanning procedure. If necessary, manually enter the barcode printed on the vials label as described in <i>Section 7: Composition of Reagent/Controls/Calibrator barcodes.</i>

Worklist loading error/malfunction messages

Error	Possible cause	Solution
Error: The number of reagents/methods exceeds the capacity of the analyzer	Worklist has more methods or reagents than can be processed	<i>Eliminate several methods</i>

Assay execution error/malfunction messages

Error	Possible cause	Solution
Message displayed: <i>Waste tank full (OK)</i>	The waste tank is full	Click on Stop and save the worklist with the tests executed up to the time of the error. The list will be marked as not executed (or partially executed) and displayed under pending lists.
Displays the message <i>Motor error (OK)</i>	The instrument encountered a hardware problem while running the test.	Click on Stop and save the worklist with the tests executed up to the time of the error. The list will be marked as not executed and displayed under pending lists.

The following errors may arise while running an assay due to lack of resources. The message for each error is given both in the *Run* page alongside the test and in the printout generated by the internal printer.

Run Page Error Message	Internal printout error message	Possible Cause	Solution
<i>Sample Level</i>	TLEV ERR (tube level error)	No liquid detected in the samples test tube or in the Control/Calibrator vial	On termination, save the list with the un-executed test and run it later.
<i>Reagent Level</i>	REAG ERR (reagent level error)	No Specific Reagent detected in the respective vial. All failed tests which require this reagent are marked with this error.	On termination, save the list with the un-executed test and run it later.
<i>Separation Level</i>	SLEV ERR (separation ag. level error)	No Separation Agent detected in the respective container. All failed tests will be marked with this error.	On termination, save the list with the un-executed test and run it later.
<i>Wash Solution Level</i>	WASH ERR (wash sol. error)	No wash solution detected in the respective bottle. All failed tests will be marked with this error.	On termination, save the list with the un-executed test and run it later.
<i>Dilution error</i>	Test result "0"	No liquid detected in the samples test tube during pre-dilution of the sample.	On termination, save the list with the un-executed test and run it later.

The following errors may arise while running the calibration procedure. The message for each error is given both in the Start page and in the execution report in correspondence with the test executed.

The error message is shown in parentheses and will be printed out on the internal printer

ECR: ECLECTICA DATA REDUCTION				
Error message (Internal printer)	Probable cause	Possible solution		
<i>Values threshold error (Acc. Error)</i> The message appears in the <i>Remark field of the Execution Report</i>: <table><tr><td>Remark</td></tr><tr><td>Acc. Error</td></tr></table>	Remark	Acc. Error	1) During execution of a worklist with samples and Controls the values of the Controls obtained are outside the accepted range. 2) During execution of a worklist with only Controls the values of the Controls obtained are outside the accepted range.	1) Run only the Controls again to obtain the results of the samples, selecting the worklist containing the controls to be executed from among the pending lists. 2) Re-run the worklist.
Remark				
Acc. Error				
<i>Curve not accepted (Crv. Rejected)</i> The message appears in the <i>Remark field of the Execution Report</i>: <table><tr><td>Remark</td></tr><tr><td>Crv. Rejected</td></tr></table>	Remark	Crv. Rejected	1) During a worklist including samples and Controls the saved curve is rejected because it is incongruent with the Control values. 2) During a worklist including only Controls the saved curve is rejected because it is incongruent with the Control values. 3) During a standardization routine the curve is not accepted.	1) Run only the Controls again to obtain the results of the samples. If the curve is rejected again, execute a standardization routine. 2) Re-run the Controls worklist. If the curve saved in the memory is rejected again, proceed as described in point 3. 3) Re-run the standardization worklist.
Remark				
Crv. Rejected				
<i>Curve accepted (Crv. Accepted)</i> The message appears in the <i>Remark field of the Execution Report in correspondence with the controls and calibrators</i> <table><tr><td>Remark</td></tr><tr><td>Crv Accepted</td></tr></table>	Remark	Crv Accepted	1) The calibration check performed by means of the two controls is in compliance with all the acceptability criteria. 2) During a standardization routine the curve has been accepted.	
Remark				
Crv Accepted				

<i>INVALID TEST</i>	The Controls or the standards were not accepted (for a new kit lot number)	1) Run again the controls/standards within 24 hours		
<i>TEMPORARY RESULT</i>	The software used an old (expired) calibration to get results.	2) Run or re-run the controls/standards within 24 hours		
<i>TEST CONFIRMED</i>	The controls/standards have been run (re-run) within 24 hours from the execution of the last worklist including the method in question	3) No action.		
<i>TEST NOT CONFIRMED</i>	The user waited more than 24 hours after getting "Invalid test" or "Temporary result"	4) No action		
<i>Values outside precision limits (Prc.err)</i> The message appears in the Remark field of the Execution Report: <table border="1"><tr><td>Remark</td></tr><tr><td>Prc.err</td></tr></table>	Remark	Prc.err	1) During execution of a worklist with samples and Controls the values of the Controls are outside the accepted range. 2) During execution of a worklist with samples and Controls the values of the Controls are out of range.	5) Run only the Controls again to obtain the results of the samples, selecting the worklist containing the controls to be executed from among the pending lists. 6) Re-run the worklist.
Remark				
Prc.err				

Invalid test results

In case of invalid test results for report purposes (sample < *Sens* or > *analytical range*):

Samples < Sensitivity:

- 1) If the sample has already been diluted, try diluting with a lower dilution factor,
- 2) If the sample has not been diluted, check that the result is in line with the case history, otherwise repeat the test,
- 3) If all results of the samples are lower than the sensitivity, this may indicate the presence of a problem on the analyzer. Contact the Adaltis Hotline Service

Samples > analytical range

- 1) If the sample has not been diluted, try diluting it.
- 2) If the sample has already been diluted, try diluting it with a higher dilution factor,
- 3) If all the results of the samples are higher than the range, there may be a problem on the analyzer. Contact the Adaltis Hotline Service

NOTE: The analyzer will indicate the sensitivity and range of the method.

Competences

Repairs and replacements in case of failure or breakage of the system must be performed exclusively by technicians authorized by Adaltis Srl.

SECTION 10

TECHNICAL SPECIFICATIONS

The ECLECTICA™ technical specifications are listed hereunder.

Dimensions and Weight

Depth: 66 cm
Height: 54 cm
Width: 85 cm
Weight: 60 kg.

Electric Requirements

Voltage: from 115V to 230V
Frequency: 50-60 Hz.

Power Consumption

200 VA (typical) – Max: 300 VA

Environmental Requirements for Operation

Temperature: 15°C to 35°C.
Humidity: 20% to 80% RH non condensing.
Height: from 0 to 2000 metres.

Environmental Requirements for Storage

Temperature: 5°C to 45°C.
Humidity: 5% to 95% RH non condensing.
Height: from 0 to 9000 metres.

Electromagnetic Compatibility - Safety

The instrument conforms to the requirements of CEI EN 61326-1:1998 - Electrical measurement, control and laboratory equipment - electromagnetic compatibility requirements and CEI EN 61010-1:1994 Safety requirements for electrical measurement, control and laboratory equipment.

Emissions

The average level of acoustic emissions is below 70 dB(A).
There are no risks concerning gas emissions, implosions or explosions of the system's parts.

Adjustments and Settings

The user is not required to set the instrument.

All mechanical and electronic adjustments must be done by Adaltis technical personnel.

Productivity

Time for first immunoassay result: from 30 to 90 min depending on scheduled tests.

Tests per hour after first result:

- 48 for Immunochemistry
- 102 tests for Clinical Chemistry

Reagents/Controls/Calibrators

Loading

Reagents/Controls/Calibrators dish:

20 reagent positions

28 control/calibrator positions.

4 Reaction Segments each with 24 Cells.

Identification

The bottles are labelled with barcodes.

Loading of data from Smart Card.

Temperature control

The reagents dish is kept at a temperature of around 15°C below ambient temperature.

Samples

Loading

60 position samples carousel (12/13 mm diameter and 50-100 mm height test tubes)

Identification

The sample barcode identification system is compatible with the following codings: "Code 128, 39 code-bar, InterLeaved 2/5, UPC/EAN".

Sampling System

The sampling system is composed of a-magnetic needles SN1 and SN2 for samples and Specific Reagents, two needles for Common Reagents, 8 needles for wash cycles and two for readings.

The system has the following precisions:

Samples sampling precisions

- Dispensing accuracy for 10 µl of sample/control: $\leq 3\%$ CV.
- Dispensing accuracy for 25 µl of sample/control: $\leq 2.5\%$ CV
- Dispensing accuracy for 50 µl of sample/control: $\leq 2.2\%$ CV
- Dispensing accuracy for 100 µl of sample/control: $\leq 2.2\%$ CV.
- Dispensing precision for reagents: $< 2.2\%$ (CV) for > 50 µl.

Dilutors: 1 dilutor with 1 precision syringe (1 ml capacity and resolution 0.3 µl).

Carry-Over: < 20 ppm

Precision: $< 6\%$.

Incubation Dish

Kept at $38^{\circ}\text{C} \pm 0.5$ for IA

Kept at $40^{\circ}\text{C} \pm 0.5$ for CC

Stability: $\pm 1^{\circ}\text{C}$

Incubation time: Programmable. Initial heating: 10 minutes.

Photometric Reading

Reading interval: $0 \div 3.0$ OD

Reading channels: 2

Reading method: horizontal type in flow Cell

Reading filters: 9 interference filters.

The standard supply is 340x2, 405x2, 492x2, 546, 578, 630.

Accuracy: $\pm 1\%$ ($0 \div 2.0$ OD) extended to 8.0 OD by means of over range filter.

Resolution: 1 mOD.

Photometer bandwidth: Bandwidth: 10 nm max

Photometer carry over: Carry over: < 10 ppm

Volume of liquid waste produced

Capacity up to 1.7L

Immunology wash

Wash procedure:

Same procedure for all assays: 2 cycles (3 separation phases)

Residual volume: Residual volume < 10 ml, homogeneity to within 5 ml.

Dispensed volume: Dispensed volume from 0.35 to 0.5 ml

Magnetic particle separation: Separation guaranteed for at least 95% of magnetic particles.

LIS interface

ASTM Communications Protocol (ref. ASTM E 1381-95)

Data format: ASTM (ref. ASTM1394-91), XML, ASCII as given in Service Manual (code: ECLP40600017V30).

Characteristics of the software

Capacity to run CC and IC assays in a single session.

Quality control software: implements Controls on three levels: Levey-Jennings and Westgaard Rules.

Hardware specifications

- 12" LCD monitor
- Network interface card
- 2 USB ports
- 1 RS232 serial port
- Supports standard inkjet or bubble-jet printers
- Internal thermal printer (80 column)
- Integrated Smart Card reader

SECTION 11

SUPPLEMENTARY INFORMATION

The present Section contains information regarding:

- Warranty Limitations
- Spare parts and purchase orders
- Order information.

Warranty Limitations

Adaltis Srl (Adaltis) guarantees all products manufactured by itself (hereinafter “Product” or “Products”), under normal conditions of use, against materials and manufacturing defects, for a period of ONE YEAR from the date of shipping from the Manufacturer to the Client (hereinafter the “Warranty Period”). During the Warranty Period, Adaltis Srl will repair or replace, at its own discretion, any defective product, on condition that the Client promptly communicates the defect to Adaltis Srl.

In the case Products delivered to distributors, the Warranty period is extended by two months.

This warranty applies exclusively to new products which have never been used and which have not, after shipment by Adaltis Srl, been damaged, altered, repaired or modified in any manner, due to negligence or other reasons, by persons not authorised to represent Adaltis, even if they have sold/worked on the product. Adaltis Srl is not liable for any Warranty obligations should any modifications or repairs have been made to the product without Adaltis Srl's express written consent.

This Warranty applies to products which replace defective products and to repaired products, for the duration of the original Warranty Period only. Unless agreed in writing by Adaltis Srl, the Warranty period cannot be extended as a result of defects or repairs. Transfer of the ownership of the product by the Client to a third party does not extend the warranty period, which remains bound by the above conditions.

The above warranty is exclusive and replaces any other guarantees. Adaltis Srl does not provide any other guarantees, explicit or implicit, regarding the product, except for the present Warranty. Without limitation to the above general information, Adaltis Srl does not guarantee the commercial value of the product nor its suitability for any particular purpose. No affirmations or interpretations not expressly contained in this document are binding on Adaltis Srl as regards the warranty.

Adaltis Srl is not liable for damages, expenses or damage to the client or third parties due to accidental causes. Adaltis Srl is bound to repair or replace the product under the circumstances specified in this document.

This Warranty does not affect any statutory rights.

List of spare parts /Accessories / Consumables

Code	Description
ECL34341000000	Samples carrousel – 60 positions
ECLS4050000028	Adaptor for sample tubes (65 pieces)
2MP000053	USB Desk-Jet Printer
ECLP4050000011	Calibrated Halogen Lamp
ECLP4050000013	Kit of Tubes
ECLP4050000014	Kit of Fuses
<i>ECLP4050000000</i>	Kit of Sampling needles
ECLP4050000008	Waste Discharge Tank
ECLP2030000002	Pack of thermal paper (1 roll)
ECLP4050000007	Pack of Reaction Segments (100 units)
1700006	Cleaning Kit
ECLP40500017V31	User manual
ECLP4050000018	ECLECTICA™ Kit Assay Manual
ECLP4050CDV31	CD containing the user manual in the available languages

Information for Orders

Contact the Adaltis home office or your local dealer.

Technical service

Technical service is provided by the Adaltis technical assistance service.

Forms

The manufacturer, Adaltis Srl, surveys the level of satisfaction attained regarding the Training Course. The user shall be kindly asked to fill in an evaluation questionnaire provided by Adaltis Customer Care at the time of installation.